



# Declaration of Conformity



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**Manufacturer Name and Address:** Albert Browne Ltd  
Chancery House  
Rayns Way  
Watermead Business Park  
Syston  
Leicester  
LE7 1PF  
UK

**Manufacturer Single Registration Number (SRN):** GB-MF-000017372

**Authorized Representative Name and Address:** STERIS Ireland Ltd  
IDA Business and Technology Park  
Tullamore  
County Offaly  
R35 X865  
Ireland

**Authorized Representative SRN:** IE-AR-000010065

**Basic UDI-DI:** See the next page of this declaration for Basic UDI-DI details.

**Product:** Process Indicators Range  
See the next page of this declaration for product details.

**Intended Purpose:** The Process Indicators Range is designed to indicate whether a load has been processed through a sterilization process by way of a colour change or other physical change. These indicators are typically either placed inside the tray, pack or pouch, to be sterilised to provide assurance that the sterilization conditions have been met, or on the outside of the tray, pack or pouch so that the processed and un-processed items can be identified at a glance. Process indicators may also be in the form of self-adhesive labels.  
The Process Indicators Range contains the following sub-ranges:  
1] Vaporised Hydrogen Peroxide indicators  
2] Steam indicators  
3] Ethylene Oxide indicators  
4] Formaldehyde indicators  
5] Peracetic Acid liquid chemical sterilant indicators  
6] Gamma Radiation indicators  
7] Dry Heat indicators

**Classification:** Class I non-sterile, non-measuring, non-reusable devices according to Rule 1 of Annex VIII

**Common Specifications Used:** N/A

**ISO 13485 Certificate(s) #:** MD 504862

**Start of CE Marking:** 2019-01-10

**Place of Issue:** Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.

**Date of Issue:** 2025-06-10

**Revision:** 36

We herewith declare that this declaration of conformity is issued under the sole responsibility of the Manufacturer and that the above-mentioned product(s) meet the provisions of REGULATION (EU) 2017/745 for Medical Devices (MDR) amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. The product has been subjected to conformity assessment procedures according to EU MDR. All supporting documentation is retained on the premises of the manufacturer.

Signed for, and behalf of Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK – See signature page below.



**Product & Basic UDI-DI:** **0724995LCPIETHYOXIND95**  
2420 - Ethylene Oxide Integrating Indicator  
2421 - Process Ethylene Oxide Indicator Spots  
2563 - BX250 Multi Variable Ethylene Oxide Sterilization Indicator

**0724995LCPIFORMHYDINDBK**  
2401 - Multi-Variable Formaldehyde Multi-Variable Control Indicator  
2402 - Process Formaldehyde Indicator Spots

**0724995LCPIGAMMARADINQT**  
3301 - Process Gamma Check Indicator Spots

**0724995LCVERFYPERACIDK4**  
LCC015 - Celerity™ Chemical Indicator for enspire™ CLCSPS  
LCC023 - Verify® Chemical Indicator for SYSTEM 1 EXPRESS/PLUS using S40™ Sterilant Concentrate  
PCC029 - Verify® Process Indicator for Reliance™ EPS Endoscope Processing System

**0724995LCVERFYSTMEORCUL**  
RK019 - Verify® Steam and EO Load Record Card

**0724995LCPISTEAMINDZK**  
2551 - Multi Variable MVI Steam Sterilization Indicator

**0724995LCPITSTCNTRLINTE**  
2302 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2317 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2340 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2341 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2342 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2375 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2470 - Emulating Des-Check Low Temperature Disinfection Indicator 93°C / 10min  
2471 - Emulating Des-Check Low Temperature Disinfection Indicator 90°C / 5min  
3103 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3104 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins Self-adhesive  
3105 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins Self-adhesive  
3107 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins Self-adhesive  
3108 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins Self-adhesive  
3702 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 9 mins  
3706 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins  
3725 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 mins Self Adhesive  
3726 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins Self Adhesive  
3727 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3737 - Emulating TST Control™ Spot with Sterilizer Record Book 121 °C / 15 mins  
3739 - Emulating TST Control™ Spot with Sterilizer Record Book 134 °C / 3.5 mins  
3760 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 min  
5006 - Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins  
5006-800 - Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins  
5017 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
121180 - Emulating TST Control™ Steam Cycle Verification Indicator 5.3 mins / 134 °C  
6610300 - TST Patient Record Card 134 °C / 5.3 mins

**0724995LCPICNTRLTUBE6K**  
7301 - Sterilizer Control Tubes Type 1 (Black Spot) 121 °C / 15 min  
7302 - Sterilizer Control Tubes Type 2 (Yellow Spot) 134 °C / 3 min  
7303 - Sterilizer Control Tubes Type 3 (Green Spot) 160 °C / 60 min  
7304 - Sterilizer Control Tubes Type 4 (Blue Spot) 180 °C / 12 min  
7305 - Sterilizer Control Tubes Type 5 (White Spot) 160 °C / 120 min, 170 °C / 65 min, 180 °C / 35 min

**0724995LCPIVYSIXCESSTK**  
PCC035 - SixCess™ 134C 5.3 Min / 121C 15 Min Indicadores / Indicator / Indicadore



# Declaration of Conformity



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## Product

### & Basic **0724995LCPIBROWNESMIND9**

**UDI-DI:** 3100 - Browne Steam Integrating Indicator Type 5  
3101 - Browne Steam Integrating Indicator Type 5  
3785-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm - Italian  
3789-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm  
3794-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm – Portuguese  
5003 - Browne Steam 2 Part Pack Control Label

### **0724995LCPIVHPINDEC**

2501 - Multi Variable VAPOUR STRIP Multi-Variable Indicator for Vaporised Hydrogen Peroxide

### **0724995LCVERIFYVHPINDNW**

PCC044 - Verify® Control Quimico VH202 / Vaporized VH202 Chemical Indicator / Indicador Quimico Vaporizado VH202  
PCC057 - Verify® HPI Vaporized VH202 Process Indicator Adhesive Label  
PCC062 - Verify® HPI Chemical Indicator

### **0724995LCCELERITYHPCIST**

PCC075 - Celerity™ HP Chemical Indicator / Indicador Quimico HP  
PCC078 - Celerity™ Vaporized VH202 Process Indicator Adhesive Label / Etiqueta Adhesiva Indicadora De Proceso Vaporized VH202  
PCC079 - Celerity™ HP Multivariable Chemical Indicator / Indicador Quimico Multivariable HP

### **0724995LCESCHESSTSTCY4A**

8793547 - Eschmann essential TST Type 6 Steam Cycle Indicator Labels



# Declaration of Conformity



Approvals:		
	<b>Technical, Техническа, Technická, Teknisk, Technisch, Τεχνικά, Reglamentos, Tehniline, Tekninen, Technique, Tehnički, Műszaki, Affari tecnici, Techninés, Tehniskā, Technische, Techniczne, Regulamentação, Reglementare, Technická, Tehnično, Teknisk, Teknik</b>	
<b>Signature:</b>	<i>Stephen Hammond</i> <small>Electronically signed by: Stephen Hammond Reason: Approver Date: Jun 10, 2025 11:17 GMT+1</small>	<b>Date:</b> <b>10/06/2025</b>
<b>Name:</b>	S. Hammond	
<b>Title:</b>	Quality Director	
	<b>Regulatory, Регулаторни, Regulace, regulering, Behördlich, Κανονιστικά, técnicos, Regulatorne, Lakisääteinen, Réglementation, Regulativni, Szabályozási, Affari regolatori, reguliavimo, Regulatīvā, Regelgeving, Prawne, técnica, tehnică, Regulačná, Regulativni razdelek, Regulatorisk, Yasal</b>	
<b>Signature:</b>	<i>R. Manford</i> <small>Electronically signed by: Richard Manford Reason: Approver Date: Jun 10, 2025 09:15 GMT+1</small>	<b>Date:</b> <b>10/06/2025</b>
<b>Name:</b>	R. Manford	
<b>Title:</b>	Regulatory Affairs Director	

<b>Име и адрес на производителя:</b>	Albert Browne Ltd Chancery House Rayns Way Watermead Business Park Syston Leicester LE7 1PF UK
<b>Единен регистрационен номер (SRN) на производителя</b>	GB-MF-000017372
<b>Наименование и адрес на упълномощения представител:</b>	STERIS Ireland Ltd IDA Business and Technology Park Tullamore County Offaly R35 X865 Ireland
<b>SRN на упълномощения представител:</b>	IE-AR-000010065
<b>Базов UDI-DI:</b>	Вижте следващата страница на тази декларация за основни подробности за UDI-DI.
<b>Продукт:</b>	Гама на индикаторите за процеса Вижте следващата страница на тази декларация за подробности за продуктите.
<b>Предназначение:</b>	Гамата на индикаторите за процеса е предназначена да показва дали даден товар е бил обработен чрез процес на стерилизация посредством промяна на цвета или друга физическа промяна. Тези индикатори обикновено се поставят вътре в тавата, опаковката или торбичката, които ще се стерилизират, за да се гарантира, че условията за стерилизация са изпълнени, или от външната страна на тавата, опаковката или торбичката, така че обработените и необработените артикули да могат да бъдат идентифицирани с един поглед. Индикаторите за процеса могат да бъдат и под формата на самозалепващи етикети. Гамата на индикаторите за процеса съдържа следните подгрупи: 1] Индикатори за изпарен водороден пероксид 2] Индикатори за пара 3] Индикатори за етиленов оксид 4] Индикатори за формалдехид 5] Течни химически стерилантни индикатори за пероцетна киселина 6] Индикатори за гама радиация 7] Индикатори за суха топлина
<b>Класификация:</b>	Клас I нестерилни еднократни изделия без измервателна функция съгласно правило 1 от Приложение VIII
<b>Използвани общи спецификации:</b>	N/A
<b>Сертификат(и) ISO 13485 №</b>	MD 504862
<b>Начало на маркировка „CE“:</b>	2019-01-10
<b>Място на издаване:</b>	Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
<b>Дата на издаване:</b>	2025-06-10
<b>Редакция:</b>	36



Заявяваме, че настоящата декларация за съответствие се издава на пълната отговорност на Производителя и гореспоменатото(ите) изделие(я) съответства(т) на разпоредбите в РЕГЛАМЕНТ (ЕО) 2017/745 за медицински изделия (РМД), изменящ Директива 2001/83/ЕО, Регламент (ЕО) № 178/2002 и Регламент (ЕО) № 1223/2009, и отменящ Директиви 90/385/ЕИО и 93/42/ЕИО на Съвета. Изделието е било подложено на процедури за оценка на съответствието съгласно РМД на ЕС. Всички допълнителни документи се съхраняват от производителя.

Подписано за и от името на Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK Вижте по-долу страницата с подписа.



<b>Изделие &amp; Основен UDI-DI (уникален идентификатор на изделие-идентификатор на изделие):</b>	<b>0724995LCPIETHYOXIND95</b>
	2563 - BX250 Multi Variable Ethylene Oxide Sterilization Indicator
	<b>0724995LCPISTCNTRLINTE</b>
	2302 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins
	2317 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins
	2340 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins
	2341 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins
	2342 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins
	2375 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins
	3103 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive
	3104 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins Self-adhesive
	3105 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins Self-adhesive
	3107 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins Self-adhesive
	3108 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins Self-adhesive
	3702 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 9 mins
	3706 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins
	3725 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 mins Self Adhesive
	3726 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins Self Adhesive
	3727 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive
	3760 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 min
	5006 - Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins
	5017 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins
	<b>0724995LCPISTEAMINDZK</b>
2551 - Multi Variable MVI Steam Sterilization Indicator	
<b>0724995LCPIBROWNESMIND9</b>	
3100 - Browne Steam Integrating Indicator Type 5	
3101 - Browne Steam Integrating Indicator Type 5	
<b>0724995LCCELERITYHPCIST</b>	
PCC075 - Celerity™ HP Chemical Indicator / Indicador Quimico HP	
PCC079 - Celerity™ HP Multivariable Chemical Indicator / Indicador Quimico Multivariable HP	
<b>0724995LCPIBROWNESMIND9</b>	
3789-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm	
<b>0724995LCPIVHPINDEC</b>	
2501 - Multi Variable VAPOUR STRIP Multi-Variable Indicator for Vaporised Hydrogen Peroxide	
<b>0724995LCPICNTRLTUBE6K</b>	
7301 - Sterilizer Control Tubes Type 1 (Black Spot) 121 °C / 15 min	
7302 - Sterilizer Control Tubes Type 2 (Yellow Spot) 134 °C / 3 min	
7303 - Sterilizer Control Tubes Type 3 (Green Spot) 160 °C / 60 min	
7304 - Sterilizer Control Tubes Type 4 (Blue Spot) 180 °C / 12 min	
7305 - Sterilizer Control Tubes Type 5 (White Spot) 160 °C / 120 min, 170 °C / 65 min, 180 °C / 35 min	
<b>0724995LCPIGAMMARADINQT</b>	
3301 - Process Gamma Check Indicator Spots	
<b>0724995LCPIFORMHYDINDBK</b>	
2401 - Multi-Variable Formaldehyde Multi-Variable Control Indicator	

<b>Název a adresa výrobce:</b>	Albert Browne Ltd Chancery House Rayns Way Watermead Business Park Syston Leicester LE7 1PF UK
<b>Jedinečné registrační číslo výrobce (SRN)</b>	GB-MF-000017372
<b>Název a adresa oprávněného zástupce:</b>	STERIS Ireland Ltd IDA Business and Technology Park Tullamore County Offaly R35 X865 Ireland
<b>SRN oprávněného zástupce:</b>	IE-AR-000010065
<b>Základní UDI-DI:</b>	Základní informace o UDI-DI naleznete na další straně tohoto prohlášení.
<b>Výrobek:</b>	Řada procesních indikátorů Podrobnosti o výrobku naleznete na další straně tohoto prohlášení.
<b>Zamýšlený účel:</b>	Řada procesních indikátorů je určena k indikaci, zda byla náplň zpracována sterilizačním procesem prostřednictvím změny barvy nebo jiné fyzikální změny. Tyto indikátory jsou obvykle umístěny buď uvnitř zásobníku, balení nebo sáčku, které mají být sterilizovány, aby bylo zajištěno, že byly splněny podmínky sterilizace, nebo na vnější straně zásobníku, balení nebo sáčku, aby bylo možné na první pohled identifikovat zpracované a nezpracované položky. Procesní indikátory mohou být také ve formě samolepicích štítků. Řada procesních indikátorů zahrnuje následující dílčí řady: 1] Indikátory odpařeného peroxidu vodíku 2] Indikátory páry 3] Indikátory ethylenoxidu 4] Indikátory formaldehydu 5] Kapalně chemické sterilizační indikátory kyseliny peroctové 6] Indikátory gama záření 7] Indikátory suchého tepla
<b>Klasifikace:</b>	Třída I nesterilní, neměřící, jednorázová zařízení, podle Pravidla 1 Přílohy VIII
<b>Použitá obecná specifikace:</b>	N/A
<b>Č. certifikátu/-ů ISO 13485:</b>	MD 504862
<b>Zahájení získání označení CE:</b>	2019-01-10
<b>Místo vystavení:</b>	Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
<b>Datum vystavení:</b>	2025-06-10
<b>Revize:</b>	36

Prohlašujeme tímto, že toto prohlášení o shodě se vydává na výhradní odpovědnost Výrobce a že výše uvedený/-é produkt(y) splňuje/-í požadavky NAŘÍZENÍ EP A RADY (EU) č. 2017/745 o zdravotnických prostředcích (MDR), změně směrnice 2001/83/ES, nařízení (ES) č. 178/2002 a nařízení (ES) č. 1223/2009 a o zrušení směrnic Rady 90/385/EHS a 93/42/EHS. Výrobek byl podroben postupům pro posouzení shody podle EU MDR. Veškerá podpůrná dokumentace je uložena v prostorách výrobce.

Podepsáno za a jménem Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK – viz podpisová stránka níže

**Výrobek 0724995LCPISTCNTRLINTE**

- &** 2302 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins
- Základní** 2317 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins
- UDI-DI:** 2340 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins
- 2341 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins
- 2342 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins
- 2375 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins
- 2470 - Emulating Des-Check Low Temperature Disinfection Indicator 93°C / 10min
- 2471 - Emulating Des-Check Low Temperature Disinfection Indicator 90°C / 5min
- 3103 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive
- 3104 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins Self-adhesive
- 3105 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins Self-adhesive
- 3107 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins Self-adhesive
- 3108 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins Self-adhesive
- 3702 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 9 mins
- 3706 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins
- 3725 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 mins Self Adhesive
- 3726 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins Self Adhesive
- 3727 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive
- 3760 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 min
- 5006 - Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins
- 5017 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins

**0724995LCPISTEAMINDZK**

- 2551 - Multi Variable MVI Steam Sterilization Indicator

**0724995LCPICNTRLTUBE6K**

- 7301 - Sterilizer Control Tubes Type 1 (Black Spot) 121 °C / 15 min
- 7302 - Sterilizer Control Tubes Type 2 (Yellow Spot) 134 °C / 3 min
- 7303 - Sterilizer Control Tubes Type 3 (Green Spot) 160 °C / 60 min
- 7304 - Sterilizer Control Tubes Type 4 (Blue Spot) 180 °C / 12 min
- 7305 - Sterilizer Control Tubes Type 5 (White Spot) 160 °C / 120 min, 170 °C / 65 min, 180 °C / 35 min

**0724995LCPIETHYXIND95**

- 2420 - Ethylene Oxide Integrating Indicator

**0724995LCPIVHPINDEC**

- 2501 - Multi Variable VAPOUR STRIP Multi-Variable Indicator for Vaporised Hydrogen Peroxide

**0724995LCCELERITYHPCIST**

- PCC075 - Celerity™ HP Chemical Indicator / Indicador Quimico HP
- PCC079 - Celerity™ HP Multivariable Chemical Indicator / Indicador Quimico Multivariable HP

**0724995LCPIBROWNESMIND9**

- 3100 - Browne Steam Integrating Indicator Type 5
- 3101 - Browne Steam Integrating Indicator Type 5
- 3789-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm

**0724995LCPIGAMMARADINQT**

- 3301 - Process Gamma Check Indicator Spots

**0724995LCPIFORMHYDINDBK**

- 2401 - Multi-Variable Formaldehyde Multi-Variable Control Indicator

**Producentens navn og adresse:** Albert Browne Ltd  
Chancery House  
Rayns Way  
Watermead Business Park  
Syston  
Leicester  
LE7 1PF  
UK

**Enkelt producentregistreringsnummer (SRN)** GB-MF-000017372

**Navn og adresse på autoriseret repræsentant:** STERIS Ireland Ltd  
IDA Business and Technology Park  
Tullamore  
County Offaly  
R35 X865  
Ireland

**Autoriseret repræsentant SRN:** IE-AR-000010065

**Basal UDI-DI:** Se næste side i denne erklæring for oplysninger om grundlæggende UDI-DI.

**Produkt:** Serien af procesindikatorer  
Se næste side i denne erklæring for detaljerede produktoplysninger.

**Tilsigtet formål:** Serien af procesindikatorer er designet til, ved hjælp af en farveændring eller anden fysisk ændring, at indikere, hvorvidt en last er blevet behandlet i en steriliseringsproces. Disse indikatorer placeres typisk enten i bakken, pakken eller posen, der skal steriliseres, for at sikre, at steriliseringsbetingelserne er blevet opfyldt, eller på ydersiden af bakken, pakken eller posen, så de behandlede og ubehandlede emner øjeblikkeligt kan identificeres. Procesindikatorerne kan også være i form af selvklæbende etiketter.

Serien af procesindikatorer omfatter følgende underserier:

- 1] Indikatorer til hydrogenperoxid i dampform
- 2] Dampindikatorer
- 3] Ethylenoxidindikatorer
- 4] Formaldehydindikatorer
- 5] Indikatorer til pereddikesyre som flydende kemisk steriliseringsmiddel
- 6] Gammastrålingsindikatorer
- 7] Indikatorer til tør varme

**Klassificering:** Klasse I ikke-steril, ikke-målende, ikke-genanvendelige enheder i henhold til regel 1 i bilag VIII

**Anvendte fællesspecifikationer:** N/A

**ISO 13485 Certifikat(er) nr.:** MD 504862

**Start på CE-mærkning:** 2019-01-10

**Udstedelsessted:** Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.

**Udstedelsesdato:** 2025-06-10

**Revidering:** 36

Vi erklærer hermed, at denne overensstemmelseserklæring er udstedt udelukkende under producentens ansvar for, at det/de ovennævnte produkt(er) lever op til bestemmelserne under REGULATIV (EF) 2017/745 for medicinsk udstyr (MDR), der ajourfører direktiv 2001/83/EU, regulativ (EU) nr. 178/2002 og regulativ (EU) nr. 1223/2009 og ophæver de lokale direktiver 90/385/EØF og 93/42/EØF. Produktet er blevet underlagt overensstemmelsesvurderingsprocedurer i overensstemmelse med EU MDR. Al supplerende dokumentation er indhentet på producentens præmisser.

Underskrevet for og på vegne af Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK - Se side for underskrift nedenfor.

**Produkt 0724995LCPISTCNTRLINTE**

<b>&amp; Basal</b>	2302 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins
<b>UDI-DI:</b>	2317 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins
	2340 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins
	2341 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins
	2342 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins
	2375 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins
	2470 - Emulating Des-Check Low Temperature Disinfection Indicator 93°C / 10min
	2471 - Emulating Des-Check Low Temperature Disinfection Indicator 90°C / 5min
	3103 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive
	3104 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins Self-adhesive
	3105 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins Self-adhesive
	3107 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins Self-adhesive
	3108 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins Self-adhesive
	3702 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 9 mins
	3706 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins
	3725 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 mins Self Adhesive
	3726 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins Self Adhesive
	3727 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive
	3737 - Emulating TST Control™ Spot with Sterilizer Record Book 121 °C / 15 mins
	3739 - Emulating TST Control™ Spot with Sterilizer Record Book 134 °C / 3.5 mins
	3760 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 min
	5006 - Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins
	5017 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins
	121180 - Emulating TST Control™ Steam Cycle Verification Indicator 5.3 mins / 134 °C

**0724995LCPICNTRLTUBE6K**

	7301 - Sterilizer Control Tubes Type 1 (Black Spot) 121 °C / 15 min
	7302 - Sterilizer Control Tubes Type 2 (Yellow Spot) 134 °C / 3 min
	7303 - Sterilizer Control Tubes Type 3 (Green Spot) 160 °C / 60 min
	7304 - Sterilizer Control Tubes Type 4 (Blue Spot) 180 °C / 12 min
	7305 - Sterilizer Control Tubes Type 5 (White Spot) 160 °C / 120 min, 170 °C / 65 min, 180 °C / 35 min

**0724995LCPIVHPINDEC**

	2501 - Multi Variable VAPOUR STRIP Multi-Variable Indicator for Vaporised Hydrogen Peroxide
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**0724995LCPISTEAMINDZK**

	2551 - Multi Variable MVI Steam Sterilization Indicator
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**0724995LCPIFORMHYDINDBK**

	2401 - Multi-Variable Formaldehyde Multi-Variable Control Indicator
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**0724995LCCELERITYHPCIST**

	PCC075 - Celerity™ HP Chemical Indicator / Indicador Quimico HP
	PCC079 - Celerity™ HP Multivariable Chemical Indicator / Indicador Quimico Multivariable HP

**0724995LCPIBROWNESMIND9**

	3100 - Browne Steam Integrating Indicator Type 5
	3101 - Browne Steam Integrating Indicator Type 5
	3789-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm

**0724995LCPIGAMMARADINQT**

	3301 - Process Gamma Check Indicator Spots
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<b>Name und Adresse des Herstellers:</b>	Albert Browne Ltd Chancery House Rayns Way Watermead Business Park Syston Leicester LE7 1PF UK
<b>Einmalige Registrierungsnummer (SRN) des Herstellers</b>	GB-MF-000017372
<b>Name und Adresse des autorisierten Vertreters:</b>	STERIS Ireland Ltd IDA Business and Technology Park Tullamore County Offaly R35 X865 Ireland
<b>SRN des autorisierten Vertreters:</b>	IE-AR-000010065
<b>Basis-UDI-DI:</b>	Auf der nächsten Seite dieser Erklärung finden Sie Details zur Basis UDI-DI.
<b>Produkt:</b>	Sortiment der Prozessindikatoren Auf der nächsten Seite dieser Erklärung finden Sie Produktdetails.
<b>Zweckbestimmung:</b>	Das Sortiment der Prozessindikatoren wurde entwickelt, um durch eine Farbänderung oder eine andere physikalische Änderung anzuzeigen, ob eine Charge im Sterilisationsprozess aufbereitet wurde. Diese Indikatoren werden in der Regel entweder in die zu sterilisierenden Siebe, Pakete oder Beutel platziert, um sicherzustellen, dass die Sterilisationsbedingungen erfüllt sind, oder an der Außenseite des Siebs, Pakets oder Beutels angebracht, damit aufbereitete und nicht aufbereitete Artikel auf einen Blick zu unterscheiden sind. Prozessindikatoren können auch selbstklebende Etiketten sein. Das Sortiment der Prozessindikatoren umfasst die folgenden Teilbereiche: 1] Indikatoren für Wasserstoffperoxid-Dampf 2] Dampfindikatoren 3] Ethylenoxidindikator 4] Formaldehyd-Indikatoren 5] Indikatoren für chemische Sterilisationsmittel aus Peressigsäure 6] Indikatoren für Gammastrahlung 7] Indikatoren für Heißluft
<b>Klassifizierung:</b>	Klasse I nicht sterile, nicht wiederverwendbare Vorrichtungen ohne Messfunktion, gemäß Regel 1 von Anhang VIII
<b>Übliche verwendete Spezifikationen:</b>	N/A
<b>ISO-13485-Zertifikat(e) Nr.:</b>	MD 504862
<b>Beginn der CE-Kennzeichnung:</b>	2019-01-10
<b>Ausstellungsort:</b>	Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
<b>Ausstellungsdatum:</b>	2025-06-10
<b>Version:</b>	36



## Konformitätserklärung



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Wir erklären hiermit, dass diese Konformitätserklärung unter der alleinigen Verantwortung des Herstellers ausgestellt wird und dass das oben genannte Produkt bzw. die oben genannten Produkte die Bestimmungen der VERORDNUNG (EU) 2017/745 für Medizinprodukte (MDR) zur Änderung der Richtlinie 2001/83/EG, der Verordnung (EG) Nr. 178/2002 und der Verordnung (EG) Nr. 1223/2009 sowie zur Aufhebung der Richtlinien 90/385/EWG und 93/42/EWG des Rates erfüllen. Das Produkt wurde den Konformitätsbewertungsverfahren gemäß EU MDR unterzogen. Die gesamte Begleitdokumentation wird beim Hersteller aufbewahrt.

Unterzeichnet für und im Namen von Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK – siehe nachfolgende Unterschriftenseite.

**Produkt** 0724995LCPIETHYOXIND95  
**&** 2420 - Ethylene Oxide Integrating Indicator  
**Basis-** 2421 - Process Ethylene Oxide Indicator Spots  
**UDI-DI:** 2563 - BX250 Multi Variable Ethylene Oxide Sterilization Indicator

**0724995LCPIFORMHYDINDBK**

2401 - Multi-Variable Formaldehyde Multi-Variable Control Indicator  
2402 - Process Formaldehyde Indicator Spots

**0724995LCVERFYPERACIDK4**

PCC029 - Verify® Process Indicator for Reliance™ EPS Endoscope Processing System

**0724995LCPISTEAMINDZK**

2551 - Multi Variable MVI Steam Sterilization Indicator

**0724995LCPITSTCNTRLINTE**

2302 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2317 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2340 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2341 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2342 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2375 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2470 - Emulating Des-Check Low Temperature Disinfection Indicator 93°C / 10min  
2471 - Emulating Des-Check Low Temperature Disinfection Indicator 90°C / 5min 3103 Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3104 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins Self-adhesive  
3105 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins Self-adhesive  
3107 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins Self-adhesive  
3108 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins Self-adhesive  
3702 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 9 mins  
3706 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins 3725 Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 mins Self Adhesive  
3726 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins Self Adhesive  
3727 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3737 - Emulating TST Control™ Spot with Sterilizer Record Book 121 °C / 15 mins  
3739 - Emulating TST Control™ Spot with Sterilizer Record Book 134 °C / 3.5 mins  
3760 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 min  
5006 - Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins  
5017 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
6610300 - TST Patient Record Card 134 °C / 5.3 mins

**0724995LCPICNTRLTUBE6K**

7301 - Sterilizer Control Tubes Type 1 (Black Spot) 121 °C / 15 min  
7302 - Sterilizer Control Tubes Type 2 (Yellow Spot) 134 °C / 3 min  
7303 - Sterilizer Control Tubes Type 3 (Green Spot) 160 °C / 60 min  
7304 - Sterilizer Control Tubes Type 4 (Blue Spot) 180 °C / 12 min  
7305 - Sterilizer Control Tubes Type 5 (White Spot) 160 °C / 120 min, 170 °C / 65 min, 180 °C / 35 min

**0724995LCPIVHPINDEC**

2501 - Multi Variable VAPOUR STRIP Multi-Variable Indicator for Vaporised Hydrogen Peroxide

**0724995LCVERIFYVHPINDNW**

PCC057 - Verify® HPI Vaporized VH202 Process Indicator Adhesive Label  
PCC062 - Verify® HPI Chemical Indicator

**0724995LCCELERITYHPCIST**

PCC075 - Celerity™ HP Chemical Indicator / Indicador Quimico HP  
PCC078 - Celerity™ Vaporized VH202 Process Indicator Adhesive Label / Etiqueta Adhesiva Indicadora De Proceso Vaporized VH202  
PCC079 - Celerity™ HP Multivariable Chemical Indicator / Indicador Quimico Multivariable HP



# Konformitätserklärung



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**Produkt**

**&** **0724995LCPIBROWNESMIND9**

**Basis-** 3100 - Browne Steam Integrating Indicator Type 5

**UDI-DI:** 3101 - Browne Steam Integrating Indicator Type 5

3789-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm

**0724995LCPIGAMMARADINQT**

3301 - Process Gamma Check Indicator Spots

<b>Όνομα και διεύθυνση κατασκευαστή:</b>	Albert Browne Ltd Chancery House Rayns Way Watermead Business Park Syston Leicester LE7 1PF UK
<b>Ενιαίος Αριθμός Καταχώρισης Κατασκευαστή (SRN)</b>	GB-MF-000017372
<b>Όνομα και διεύθυνση εξουσιοδοτημένου αντιπροσώπου:</b>	STERIS Ireland Ltd IDA Business and Technology Park Tullamore County Offaly R35 X865 Ireland
<b>SRN εξουσιοδοτημένου αντιπροσώπου:</b>	IE-AR-0000100065
<b>Βασικός UDI-DI:</b>	Δείτε την επόμενη σελίδα αυτής της δήλωσης για τις λεπτομέρειες του βασικού UDI-DI.
<b>Προϊόν:</b>	Σύστημα δεικτών συσκευής προσομοίωσης Δείτε την επόμενη σελίδα αυτής της δήλωσης για τις λεπτομέρειες του προϊόντος.
<b>Προβλεπόμενος σκοπός:</b>	<p>Το σύστημα δεικτών συσκευής προσομοίωσης έχει επινοηθεί για να υποδεικνύει εάν ένα φορτίο έχει υποστεί επεξεργασία μέσω μιας διαδικασίας αποστείρωσης με αλλαγή χρώματος ή άλλη φυσική μεταβολή. Αυτοί οι δείκτες τοποθετούνται συνήθως είτε στο εσωτερικό του δίσκου, της συσκευασίας ή της σακούλας, προς αποστείρωση προκειμένου να παρέχεται η βεβαιότητα ότι πληρούνται οι συνθήκες αποστείρωσης, είτε στο εξωτερικό του δίσκου, της συσκευασίας ή της σακούλας έτσι ώστε τα επεξεργασμένα και μη επεξεργασμένα αντικείμενα να μπορούν να προσδιορίζονται με μια ματιά. Οι δείκτες συσκευής προσομοίωσης μπορεί επίσης να έχουν τη μορφή αυτοκόλλητων ετικετών.</p> <p>Το σύστημα δεικτών συσκευής προσομοίωσης περιλαμβάνει τα ακόλουθα υποσύνολα:</p> <ol style="list-style-type: none"><li>1] Δείκτες εξαμιζόμενου υπεροξειδίου του υδρογόνου</li><li>2] Δείκτες ατμού</li><li>3] Δείκτες οξειδίου του αιθυλενίου</li><li>4] Δείκτες φορμαλδεΰδης</li><li>5] Δείκτες υγρού χημικού αποστειρωτικού υπεροξικού οξέος</li><li>6] Δείκτες ακτινοβολίας γάμμα</li><li>7] Δείκτες ξηρής θερμότητας</li></ol>
<b>Ταξινόμηση:</b>	Κλάση συσκευές κλάσης I μη αποστειρωμένες, χωρίς οργανολογία μέτρησης και μη επαναχρησιμοποιούμενες σύμφωνα με τον Κανόνα 1 του Παραρτήματος VIII
<b>Κοινές προδιαγραφές που χρησιμοποιούνται:</b>	N/A
<b>Πιστοποιητικό(-ά) ISO 13485 #:</b>	MD 504862
<b>Έναρξη σήμανσης CE:</b>	2019-01-10
<b>Τόπος έκδοσης:</b>	Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
<b>Ημερομηνία έκδοσης:</b>	2025-06-10
<b>Αναθεώρηση:</b>	36

Δηλώνουμε με το παρόν ότι η παρούσα δήλωση συμμόρφωσης εκδίδεται με αποκλειστική ευθύνη του Κατασκευαστή και ότι το(-α) προαναφερόμενο(-α) προϊόν(-τα) συμμορφώνεται(-ονται) με τις διατάξεις του ΚΑΝΟΝΙΣΜΟΥ (ΕΕ) 2017/745 για τα ιατροτεχνολογικά προϊόντα (MDR), για την τροποποίηση της οδηγίας 2001/83/ΕΚ, του κανονισμού (ΕΚ) αριθ. 178/2002 και του κανονισμού (ΕΚ) αριθ. 1223/2009 και για την κατάργηση των οδηγιών του Συμβουλίου 90/385/ΕΟΚ και 93/42/ΕΟΚ. Το προϊόν έχει υποβληθεί σε διαδικασίες αξιολόγησης συμμόρφωσης σύμφωνα με τον κανονισμό ΕΕ MDR. Όλα τα δικαιολογητικά έγγραφα διατηρούνται στις εγκαταστάσεις του κατασκευαστή.

Υπογραφή για λογαριασμό του/της Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK – Βλ. σελίδα υπογραφών παρακάτω.

**Προϊόν & Βασικός UDI-DI:** **0724995LCPISTEAMINDZK**  
2551 - Multi Variable MVI Steam Sterilization Indicator

**0724995LCCELERITYHPCIST**  
PCC075 - Celerity™ HP Chemical Indicator / Indicador Quimico HP  
PCC079 - Celerity™ HP Multivariable Chemical Indicator / Indicador Quimico Multivariable HP

**0724995LCPIBROWNESMIND9**  
3100 - Browne Steam Integrating Indicator Type 5  
3101 - Browne Steam Integrating Indicator Type 5  
3789-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm

**0724995LCPIVHPINDEC**  
2501 - Multi Variable VAPOUR STRIP Multi-Variable Indicator for Vaporised Hydrogen Peroxide

**0724995LCPICNTRLTUBE6K**  
7301 - Sterilizer Control Tubes Type 1 (Black Spot) 121 °C / 15 min  
7302 - Sterilizer Control Tubes Type 2 (Yellow Spot) 134 °C / 3 min  
7303 - Sterilizer Control Tubes Type 3 (Green Spot) 160 °C / 60 min  
7304 - Sterilizer Control Tubes Type 4 (Blue Spot) 180 °C / 12 min  
7305 - Sterilizer Control Tubes Type 5 (White Spot) 160 °C / 120 min, 170 °C / 65 min, 180 °C / 35 min

**0724995LCPIGAMMARADINQT**  
3301 - Process Gamma Check Indicator Spots

**0724995LCPIFORMHYDINDBK**  
2401 - Multi-Variable Formaldehyde Multi-Variable Control Indicator

**0724995LCPITSTCNTRLINTE**  
2302 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2317 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2340 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2341 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2342 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2375 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
3103 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3104 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins Self-adhesive  
3105 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins Self-adhesive  
3107 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins Self-adhesive  
3108 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins Self-adhesive  
3702 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 9 mins  
3706 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins  
3725 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 mins Self Adhesive  
3726 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins Self Adhesive  
3727 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3760 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 min

<b>Nombre y dirección del fabricante:</b>	Albert Browne Ltd Chancery House Rayns Way Watermead Business Park Syston Leicester LE7 1PF UK
<b>Número de registro único (NRU) del fabricante:</b>	GB-MF-000017372
<b>Nombre y dirección del representante autorizado:</b>	STERIS Ireland Ltd IDA Business and Technology Park Tullamore County Offaly R35 X865 Ireland
<b>NRU Representante autorizado:</b>	IE-AR-000010065
<b>UDI-DI básico:</b>	Consulte la página siguiente de esta declaración para conocer los detalles básicos del UDI-DI.
<b>Producto:</b>	Process Indicators Range Consulte la página siguiente de esta declaración para conocer los detalles de los productos.
<b>Finalidad prevista:</b>	La gama de indicadores de proceso se utiliza para demostrar, mediante un cambio de color u otro cambio físico, si una carga ha estado expuesta a un proceso de esterilización. Normalmente, estos indicadores se colocan dentro de la bandeja, el paquete o la bolsa a esterilizar para garantizar que se cumplan las condiciones de esterilización, o bien en el exterior de la bandeja, el paquete o la bolsa para distinguir de un vistazo qué elementos se han procesado y cuáles no. Los indicadores de proceso también se comercializan en formato de etiquetas autoadhesivas. La gama de indicadores de proceso está compuesta por la siguiente subgama: <ol style="list-style-type: none"><li>1) Indicadores de peróxido de hidrógeno vaporizado</li><li>2) Indicadores de vapor</li><li>3) Indicadores de óxido de etileno</li><li>4) Indicadores de formaldehído</li><li>5) Indicadores de esterilizante químico líquido de ácido peracético</li><li>6) Indicadores de radiación gamma</li><li>7) Indicadores de calor seco</li></ol>
<b>Clasificación:</b>	Clase I no estéril, dispositivos sin función de medición, no reutilizables según la regla 1 del anexo VIII
<b>Especificaciones comunes utilizadas:</b>	N/A
<b>N.º de certificado(s) ISO 13485:</b>	MD 504862
<b>Inicio de la marca CE:</b>	2019-01-10
<b>Lugar de expedición:</b>	Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
<b>Fecha de expedición:</b>	2025-06-10
<b>Revisión:</b>	36



## Declaración De Conformidad



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Por la presente manifestamos que esta declaración de conformidad se emite bajo la exclusiva responsabilidad del fabricante y que los productos mencionados cumplen las disposiciones del REGLAMENTO (UE) 2017/745 de dispositivos médicos (MDR, por sus siglas en inglés) por el que se modifican la Directiva 2001/83/CE, el Reglamento (CE) n.º 178/2002 y el Reglamento (CE) n.º 1223/2009 y se derogan las Directivas 90/385/CEE y 93/42/CEE del Consejo. El producto se ha sometido a procedimientos de evaluación de la conformidad de acuerdo con el MDR de la UE. Toda la documentación de apoyo se conserva en las instalaciones del fabricante.

Firmado en nombre y representación de Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK - Véase la página de firmas más abajo.

**Producto & UDI-DI básico:** **0724995LCPIETHYOXIND95**  
2420 - Ethylene Oxide Integrating Indicator  
2421 - Process Ethylene Oxide Indicator Spots  
2563 - BX250 Multi Variable Ethylene Oxide Sterilization Indicator

**0724995LCPIFORMHYDINDBK**  
2401 - Multi-Variable Formaldehyde Multi-Variable Control Indicator  
2402 - Process Formaldehyde Indicator Spots

**0724995LCVERFYPERACIDK4**  
LCC015 - Celerity™ Chemical Indicator for enspire™ CLCSPS  
LCC023 - Verify® Chemical Indicator for SYSTEM 1 EXPRESS/PLUS using S40™ Sterilant Concentrate  
PCC029 - Verify® Process Indicator for Reliance™ EPS Endoscope Processing System

**0724995LCPISTEAMINDZK**  
2551 - Multi Variable MVI Steam Sterilization Indicator

**0724995LCPITSTCNTRLINTE**  
2302 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2317 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2340 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2341 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2342 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2375 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2470 - Emulating Des-Check Low Temperature Disinfection Indicator 93°C / 10min  
2471 - Emulating Des-Check Low Temperature Disinfection Indicator 90°C / 5min  
3103 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3104 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins Self-adhesive  
3105 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins Self-adhesive  
3107 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins Self-adhesive  
3108 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins Self-adhesive  
3702 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 9 mins  
3706 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins  
3725 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 mins Self Adhesive  
3726 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins Self Adhesive  
3727 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3737 - Emulating TST Control™ Spot with Sterilizer Record Book 121 °C / 15 mins  
3739 - Emulating TST Control™ Spot with Sterilizer Record Book 134 °C / 3.5 mins  
3760 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 min  
5006 - Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins  
5017 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins

**0724995LCPICNTRLTUBE6K**  
7301 - Sterilizer Control Tubes Type 1 (Black Spot) 121 °C / 15 min  
7302 - Sterilizer Control Tubes Type 2 (Yellow Spot) 134 °C / 3 min  
7303 - Sterilizer Control Tubes Type 3 (Green Spot) 160 °C / 60 min  
7304 - Sterilizer Control Tubes Type 4 (Blue Spot) 180 °C / 12 min  
7305 - Sterilizer Control Tubes Type 5 (White Spot) 160 °C / 120 min, 170 °C / 65 min, 180 °C / 35 min

**0724995LCPIVHPINDEC**  
2501 - Multi Variable VAPOUR STRIP Multi-Variable Indicator for Vaporised Hydrogen Peroxide

**0724995LCVERIFYVHPINDNW**  
PCC044 - Verify® Control Quimico VH202 / Vaporized VH202 Chemical Indicator / Indicador Quimico Vaporizado VH202  
PCC057 - Verify® HPI Vaporized VH202 Process Indicator Adhesive Label  
PCC062 - Verify® HPI Chemical Indicator



**Producto & UDI-DI básico:** **0724995LCCELERITYHPCIST**  
PCC075 - Celerity™ HP Chemical Indicator / Indicador Quimico HP  
PCC078 - Celerity™ Vaporized VH202 Process Indicator Adhesive Label / Etiqueta Adhesiva Indicadora De Proceso Vaporized VH202  
PCC079 - Celerity™ HP Multivariable Chemical Indicator / Indicador Quimico Multivariable HP

**0724995LCPIVFYSIXCESSTK**  
PCC035 - SixCess™ 134C 5.3 Min / 121C 15 Min Indicadores / Indicator / Indicadore

**0724995LCPIBROWNESMIND9**  
3100 - Browne Steam Integrating Indicator Type 5  
3101 - Browne Steam Integrating Indicator Type 5  
3789-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm

**0724995LCPIGAMMARADINQT**  
3301 - Process Gamma Check Indicator Spots

<b>Tootja nimi ja address:</b>	Albert Browne Ltd Chancery House Rayns Way Watermead Business Park Syston Leicester LE7 1PF UK
<b>Tootja unikaalne registreerimisnumber (SRN):</b>	GB-MF-000017372
<b>Volitatud esindaja nimi ja address:</b>	STERIS Ireland Ltd IDA Business and Technology Park Tullamore County Offaly R35 X865 Ireland
<b>Volitatud esindaja SRN:</b>	IE-AR-000010065
<b>Põhi-UDI-DI:</b>	UDI-DI põhiaandmed leiata käesoleva avalduse järgmiselt leheküljelt.
<b>Toode:</b>	Töötlemisindikaatorite tootevalik Toote üksikasjad leiata käesoleva avalduse järgmiselt lehelt.
<b>Sihotstarve:</b>	Töötlemisindikaatorite tootevalik on mõeldud näitama, kas koormust on töödeldud steriliseerimisprotsessi käigus värvimuutuse või muu füüsilise muutuse abil. Kõnealused indikaatorid paigutatakse tavaliselt kas alusele, pakendisse või kotti steriliseerimiseks, et tagada steriliseerimistingimuste täitmine, või aluse, pakendi või koti välisküljele, et töödeldud ja töötlemata esemeid oleks võimalik kiiresti tuvastada. Töötlemisindikaatorid võivad olla ka isekleepuvate siltide kujul. Töötlemisindikaatorite tootevalik sisaldab järgmisi alamvalikuid: 1] Aurustunud vesinikperoksiidi indikaatorid 2] Auruindikaatorid 3] Etüleenoksiidi indikaatorid 4] Formaldehüüdi indikaatorid 5] Peräädikhappe vedela keemilise steriliseerimise indikaatorid 6] Gammakiirguse indikaatorid 7] Kuiva kuumuse indikaatorid
<b>Klassifikatsioon:</b>	Klass I mittesteriilsed mõõtefunktsioonita ühekordselt kasutatavad seadmed VIII lisa reegli 1 põhjal
<b>Kasutatud ühtsed kirjeldused:</b>	N/A
<b>ISO 13485 sertifikaadi (sertifikaatide) nr:</b>	MD 504862
<b>CE-märgistuse algus:</b>	2019-01-10
<b>Väljaandmise koht:</b>	Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
<b>Väljaandmise kuupäev:</b>	2025-06-10
<b>Versioon:</b>	36

Kinnitame, et siinne vastavusdeklaratsioon on avaldatud tootja ainuvastutusel ning eelnimetatud tooted on kooskõlas määrusega (EL) 2017/745, milles käsitletakse meditsiiniseadmeid, millega muudetakse direktiivi 2001/83/EÜ, määrust (EÜ) nr 178/2002 ja määrust (EÜ) nr 1223/2009 ning millega tunnistatakse kehtetuks nõukogu direktiivid 90/385/EMÜ ja 93/42/EMÜ. Toode on läbinud vastavushindamise kooskõlas Euroopa Liidu meditsiiniseadmete määrusega. Kõiki tõendavaid dokumente säilitatakse tootja territooriumil.

Allkirjastatud Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK eest ja nimel – vt allkirja lehekülg allpool.

**Toode 0724995LCPISTCNTRLINTE**

**& Põhi-UDI-DI:** 2302 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2317 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2340 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2341 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2342 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2375 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2470 - Emulating Des-Check Low Temperature Disinfection Indicator 93°C / 10min  
2471 - Emulating Des-Check Low Temperature Disinfection Indicator 90°C / 5min  
3103 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3104 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins Self-adhesive  
3105 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins Self-adhesive  
3107 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins Self-adhesive  
3108 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins Self-adhesive  
3702 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 9 mins  
3706 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins  
3725 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 mins  
Self Adhesive  
3726 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
Self Adhesive  
3727 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3760 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 min  
5006 - Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins  
5017 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
121180 - Emulating TST Control™ Steam Cycle Verification Indicator 5.3 mins / 134 °C

**0724995LCPISTEAMINDZK**

2551 - Multi Variable MVI Steam Sterilization Indicator

**0724995LCPIFORMHYDINDBK**

2401 - Multi-Variable Formaldehyde Multi-Variable Control Indicator

**0724995LCPIETHYOXIND95**

2420 - Ethylene Oxide Integrating Indicator

**0724995LCPIBROWNESMIND9**

3100 - Browne Steam Integrating Indicator Type 5

3101 - Browne Steam Integrating Indicator Type 5

3789-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm

**Vaporised Hydrogen Peroxide indicators – 0724995LCPIVHPINDEC**

2501 - Multi Variable VAPOUR STRIP Multi-Variable Indicator for Vaporised Hydrogen Peroxide

**0724995LCPICNTRLTUBE6K**

7301 - Sterilizer Control Tubes Type 1 (Black Spot) 121 °C / 15 min

7302 - Sterilizer Control Tubes Type 2 (Yellow Spot) 134 °C / 3 min

7303 - Sterilizer Control Tubes Type 3 (Green Spot) 160 °C / 60 min

7304 - Sterilizer Control Tubes Type 4 (Blue Spot) 180 °C / 12 min

7305 - Sterilizer Control Tubes Type 5 (White Spot) 160 °C / 120 min, 170 °C / 65 min, 180 °C / 35 min

**0724995LCPIGAMMARADINQT**

3301 - Process Gamma Check Indicator Spots

<b>Valmistajan nimi ja osoite:</b>	Albert Browne Ltd Chancery House Rayns Way Watermead Business Park Syston Leicester LE7 1PF UK
<b>Valmistajan yksilöllinen rekisteröintitunnus (SRN)</b>	GB-MF-000017372
<b>Valtuutetun edustajan nimi ja osoite:</b>	STERIS Ireland Ltd IDA Business and Technology Park Tullamore County Offaly R35 X865 Ireland
<b>Valtuutetun edustajan SRN:</b>	IE-AR-000010065
<b>Perustasoinen UDI-DI:</b>	Katso UDI-DI-perustiedot tämän vakuutuksen seuraavalta sivulta.
<b>Tuote:</b>	Prosessi-indikaattorien valikoima Katso tuotetiedot tämän vakuutuksen seuraavalta sivulta.
<b>Käyttötarkoitus:</b>	Prosessi-indikaattorivalikoima on tarkoitettu osoittamaan värienvaihdon tai muun fyysisen muutoksen avulla, onko kuorma käsitelty sterilointiprosessissa. Indikaattorit sijoitetaan tyypillisesti joko steriloitavan korin, pakkauksen tai pussin sisälle, kun tarkoituksena on varmistaa, että sterilointiolosuhteet täyttyvät. Indikaattorit voidaan sijoittaa myös korin, pakkauksen tai pussin ulkopuolelle, jolloin käsitellyt ja käsittelemättömät tuotteet voidaan tunnistaa yhdellä silmäyksellä. Prosessi-indikaattorit voivat olla myös itsekiinnittyviä tarroja. Prosessi-indikaattorivalikoimaan sisältyy seuraavat alivalikoimat: 1] Höyrystettyyn vetyperoksidiin perustuvat indikaattorit 2] Höyryindikaattorit 3] Etyleenioksidi-indikaattorit 4] Formaldehydi-indikaattorit 5] Peretikkahappoon perustuvan nestemäisen kemiallisen sterilointiaineen indikaattorit 6] Gammasäteilyindikaattorit 7] Kuumailmaindikaattorit
<b>Luokitus:</b>	Luokan I epästeriilit, ei uudelleenkäytettävät laitteet liitteen VIII säännön 1 mukaan
<b>Yleiset käytetyt tekniset tiedot:</b>	N/A
<b>ISO 13485 -sertifikaattien numerot:</b>	MD 504862
<b>CE-merkinnän alkamispäivämäärä:</b>	2019-01-10
<b>Myöntämipaikka:</b>	Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
<b>Myöntämispäivämäärä:</b>	2025-06-10
<b>Tarkistus:</b>	36



Ilmoitamme täten, että tämä vaatimustenmukaisuusvakuutus on julkaistu valmistajan yksinomaisella vastuulla ja yllä mainitut tuotteet noudattavat Euroopan parlamentin ja neuvoston ASETUSTA (EU) 2017/745 lääkinällisistä laitteista (MDR), joka muuttaa direktiiviä 2001/83/EY, asetusta (EY) N:o 178/2002 ja asetusta (EY) N:o 1223/2009 ja kumoaa neuvoston direktiivit 90/385/ETY ja 93/42/ETY. Tuote on arvioitu vaatimustenmukaisuuden arviointitoimenpiteillä EU MDR:n perusteella. Kaikki tukiasiakirjat säilytetään valmistajan tiloissa.

Allekirjoitettu Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK nimissä ja puolesta – Katso alla oleva allekirjoitussivu.

**Tuote &  
Perustasoinen  
UDI-DI:****0724995LCPIETHYOXIND95**

2563 - BX250 Multi Variable Ethylene Oxide Sterilization Indicator

**0724995LCPISTCNTRLINTE**

2302 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins

2317 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins

2340 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins

2341 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins

2342 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins

2375 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins

2470 - Emulating Des-Check Low Temperature Disinfection Indicator 93°C / 10min

2471 - Emulating Des-Check Low Temperature Disinfection Indicator 90°C / 5min

3103 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive

3104 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins Self-adhesive

3105 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins Self-adhesive

3107 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins Self-adhesive

3108 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins Self-adhesive

3702 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 9 mins

3706 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins

3725 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 mins Self Adhesive

3726 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins Self Adhesive

3727 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive

3760 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 min

5006 - Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins

5017 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins

121180 - Emulating TST Control™ Steam Cycle Verification Indicator 5.3 mins / 134 °C

**0724995LCPISTEAMINDZK**

2551 - Multi Variable MVI Steam Sterilization Indicator

**0724995LCPICNTRLTUBE6K**

7301 - Sterilizer Control Tubes Type 1 (Black Spot) 121 °C / 15 min

7302 - Sterilizer Control Tubes Type 2 (Yellow Spot) 134 °C / 3 min

7303 - Sterilizer Control Tubes Type 3 (Green Spot) 160 °C / 60 min

7304 - Sterilizer Control Tubes Type 4 (Blue Spot) 180 °C / 12 min

7305 - Sterilizer Control Tubes Type 5 (White Spot) 160 °C / 120 min, 170 °C / 65 min, 180 °C / 35 min

**0724995LCPIVHPINDEC**

2501 - Multi Variable VAPOUR STRIP Multi-Variable Indicator for Vaporised Hydrogen Peroxide

**0724995LCVERIFYVHPINDNW**

PCC057 - Verify® HPI Vaporized VH202 Process Indicator Adhesive Label

PCC062 - Verify® HPI Chemical Indicator

**0724995LCCELERITYHPCIST**

PCC075 - Celerity™ HP Chemical Indicator / Indicador Quimico HP

PCC078 - Celerity™ Vaporized VH202 Process Indicator Adhesive Label / Etiqueta Adhesiva Indicadora De Proceso Vaporized VH202

PCC079 - Celerity™ HP Multivariable Chemical Indicator / Indicador Quimico Multivariable HP

**0724995LCPIFORMHYDINDBK**

2401 - Multi-Variable Formaldehyde Multi-Variable Control Indicator



**0724995LCPIBROWNESMIND9**

3100 - Browne Steam Integrating Indicator Type 5

3101 - Browne Steam Integrating Indicator Type 5

3789-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm

**0724995LCPIGAMMARADINQT**

3301 - Process Gamma Check Indicator Spots

<b>Nom et adresse du fabricant:</b>	Albert Browne Ltd Chancery House Rayns Way Watermead Business Park Syston Leicester LE7 1PF UK
<b>Numéro d'enregistrement unique du fabricant (NEU):</b>	GB-MF-000017372
<b>Nom et adresse du représentant autorisé:</b>	STERIS Ireland Ltd IDA Business and Technology Park Tullamore County Offaly R35 X865 Ireland
<b>NEU du représentant autorisé:</b>	IE-AR-000010065
<b>IUD-ID de base:</b>	Reportez-vous à la page suivante de cette déclaration pour les détails de l'UDI-DI de base.
<b>Produit:</b>	Process Indicators Range Reportez-vous à la page suivante de cette déclaration pour les détails du produit.
<b>Fins prévues:</b>	La gamme d'indicateurs de procédé est conçue pour indiquer si une charge a été traitée par un procédé de stérilisation grâce à un changement de couleur ou autre changement physique. Ces indicateurs sont généralement placés à l'intérieur du plateau, de l'emballage ou du sachet à stériliser pour garantir que les conditions de stérilisation ont été respectées, ou à l'extérieur du plateau, de l'emballage ou du sachet pour pouvoir identifier d'un coup d'œil les articles traités et non traités. Les indicateurs de procédé peuvent également se présenter sous la forme d'étiquettes autocollantes. La gamme d'indicateurs de procédé contient les sous-gammes suivantes: 1] Indicateurs de peroxyde d'hydrogène vaporisé 2] Indicateurs de vapeur 3] Indicateurs d'oxyde d'éthylène 4] Indicateurs de test du formaldéhyde 5] Indicateurs de stérilisation chimique liquide à l'acide peracétique 6] Indicateurs de rayonnement gamma 7] Indicateurs de chaleur sèche
<b>Classification:</b>	Classe I dispositifs non stériles, non mesurables et non réutilisables conformément à la règle 1 de l'annexe VIII
<b>Spécifications communes utilisées:</b>	N/A
<b>ISO 13485 Numéro de certificat(s) :</b>	MD 504862
<b>Début du marquage CE:</b>	2019-01-10
<b>Lieu de délivrance:</b>	Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
<b>Date d'émission:</b>	2025-06-10
<b>Révision:</b>	36



## Déclaration de Conformité



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Nous déclarons par la présente que cette déclaration de conformité est établie sous la seule responsabilité du fabricant et que le ou les produits susmentionnés satisfont aux dispositions du règlement (UE) 2017/745 relatif aux dispositifs médicaux (MDR) modifiant la directive 2001/83/CE, le règlement (CE) no 178/2002 et le règlement (CE) no 1223/2009 et abrogeant les directives du Conseil 90/385/CEE et 93/42/CEE. Ce produit a été soumis aux procédures d'évaluation de la conformité selon l'EU MDR. L'ensemble de la documentation justificative est conservée dans les locaux du fabricant.

Signé pour et au nom de Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK - Voir la page de signature ci-dessous.

**Produit & IUD-ID de base:** **0724995LCPIETHYOXIND95**  
2420 - Ethylene Oxide Integrating Indicator  
2421 - Process Ethylene Oxide Indicator Spots  
2563 - BX250 Multi Variable Ethylene Oxide Sterilization Indicator

**0724995LCPIFORMHYDINDBK**  
2401 - Multi-Variable Formaldehyde Multi-Variable Control Indicator  
2402 - Process Formaldehyde Indicator Spots

**0724995LCVERFYPERACIDK4**  
LCC015 - Celerity™ Chemical Indicator for enspire™ CLCSPS  
LCC023 - Verify® Chemical Indicator for SYSTEM 1 EXPRESS/PLUS using S40™ Sterilant Concentrate  
PCC029 - Verify® Process Indicator for Reliance™ EPS Endoscope Processing System

**0724995LCVERFYSTMEORCUL**  
RK019 - Verify® Steam and EO Load Record Card

**0724995LCPISTEAMINDZK**  
2551 - Multi Variable MVI Steam Sterilization Indicator

**0724995LCPITSTCNTRLINTE**  
2302 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2317 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2340 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2341 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2342 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2375 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2470 - Emulating Des-Check Low Temperature Disinfection Indicator 93°C / 10min  
2471 - Emulating Des-Check Low Temperature Disinfection Indicator 90°C / 5min  
3103 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3104 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins Self-adhesive  
3105 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins Self-adhesive  
3107 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins Self-adhesive  
3108 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins Self-adhesive  
3702 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 9 mins  
3706 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins  
3725 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 mins Self Adhesive  
3726 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins Self Adhesive  
3727 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3737 - Emulating TST Control™ Spot with Sterilizer Record Book 121 °C / 15 mins  
3739 - Emulating TST Control™ Spot with Sterilizer Record Book 134 °C / 3.5 mins  
3760 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 min  
5006 - Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins  
5017 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins

**0724995LCPICNTRLTUBE6K**  
7301 - Sterilizer Control Tubes Type 1 (Black Spot) 121 °C / 15 min  
7302 - Sterilizer Control Tubes Type 2 (Yellow Spot) 134 °C / 3 min  
7303 - Sterilizer Control Tubes Type 3 (Green Spot) 160 °C / 60 min  
7304 - Sterilizer Control Tubes Type 4 (Blue Spot) 180 °C / 12 min  
7305 - Sterilizer Control Tubes Type 5 (White Spot) 160 °C / 120 min, 170 °C / 65 min, 180 °C / 35 min

**0724995LCPIVHPINDEC**  
2501 - Multi Variable VAPOUR STRIP Multi-Variable Indicator for Vaporised Hydrogen Peroxide

**0724995LCVERIFYVHPINDNW**  
PCC057 - Verify® HPI Vaporized VH202 Process Indicator Adhesive Label  
PCC062 - Verify® HPI Chemical Indicator



## Déclaration de Conformité



fr

### Produit

#### **& IUD- 0724995LCCELERITYHPCIST**

**ID de** PCC075 - Celerity™ HP Chemical Indicator / Indicador Quimico HP

**base:** PCC078 - Celerity™ Vaporized VH202 Process Indicator Adhesive Label / Etiqueta Adhesiva Indicadora De Proceso Vaporized VH202  
PCC079 - Celerity™ HP Multivariable Chemical Indicator / Indicador Quimico Multivariable HP

#### **0724995LCPIBROWNESMIND9**

3100 - Browne Steam Integrating Indicator Type 5

3101 - Browne Steam Integrating Indicator Type 5

3789-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm

#### **0724995LCPIGAMMARADINQT**

3301 - Process Gamma Check Indicator Spots

<b>Naziv i adresa proizvođača:</b>	Albert Browne Ltd Chancery House Rayns Way Watermead Business Park Syston Leicester LE7 1PF UK
<b>Jedinstveni registracijski broj proizvođača (SRN)</b>	GB-MF-000017372
<b>Naziv i adresa ovlaštenog zastupnika:</b>	STERIS Ireland Ltd IDA Business and Technology Park Tullamore County Offaly R35 X865 Ireland
<b>SRN ovlaštenog zastupnika:</b>	IE-AR-000010065
<b>Osnovni UDI-DI:</b>	Pojedinosti o osnovnom jedinstvenom identifikatoru (UDI-DI-ju) potražite na sljedećoj stranici ove izjave.
<b>Proizvod:</b>	Asortiman procesnih indikatora Pojedinosti o proizvodu potražite na sljedećoj stranici ove izjave.
<b>Namjenska upotreba:</b>	Asortiman procesnih indikatora osmišljen je kako bi promjenom boje ili drugom fizičkom promjenom pokazao je li punjenje obrađeno postupkom sterilizacije. Ti se indikatori obično stavljaju u podložak, pakiranje ili vrećicu koji se steriliziraju kako bi se provjerilo jesu li ispunjeni uvjeti za sterilizacije, ili s vanjske strane podloška, pakiranja ili vrećice kako bi se obrađeni i neobrađeni predmeti mogli brzo identificirati. Procesni indikatori mogu biti i u obliku samoljepljivih oznaka. Asortiman procesnih indikatora uključuje sljedeći dodatni asortiman: 1] Indikatori za ispareni vodikov peroksid 2] Indikatori za paru 3] Indikatori za etilen-oksidi 4] Indikatori za formaldehid 5] Indikatori za tekuće kemijsko sredstvo za sterilizaciju na bazi peroctene kiseline 6] Indikatori za gama zračenje 7] Indikatori za suhi vrući zrak
<b>Razvrstavanje:</b>	Klasa nesterilni proizvodi za jednokratnu uporabu bez mjerne funkcije I klase u skladu s pravilom 1 iz Priloga VIII
<b>Korištene zajedničke specifikacije:</b>	N/A
<b>Br. ISO 13485 certifikata:</b>	MD 504862
<b>Početak označavanja oznakom CE:</b>	2019-01-10
<b>Mjesto izdavanja:</b>	Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
<b>Datum izdavanja:</b>	2025-06-10
<b>Revizija:</b>	36

Ovime izjavljujemo da se ova izjava o sukladnosti izdaje na isključivu odgovornost proizvođača i da prethodno navedeni proizvod(i) ispunjava(ju) odredbe UREDBE (EU) 2017/745 o medicinskim proizvodima (MDR), o izmjeni Direktive 2001/83/EZ, Uredbe (EZ) br. 178/2002 i Uredbe (EZ) br. 1223/2009 te o stavljanju izvan snage direktiva Vijeća 90/385/EEZ i 93/42/EEZ. Na ovom je proizvodu primijenjen postupak ocjenjivanja sukladnosti u skladu s Uredbom o medicinskim proizvodima EU-a. Sva popratna dokumentacija čuva se u prostorima proizvođača.

Potpisano za i u ime Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK: pogledati stranicu s potpisima u nastavku.

**Proizvod 0724995LCPISTCNTRLINTE**

- &** 2302 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins
- Osnovni**
- UDI-DI:** 2317 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2340 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2341 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2342 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2375 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
3103 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3104 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins Self-adhesive  
3105 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins Self-adhesive  
3107 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins Self-adhesive  
3108 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins Self-adhesive  
3702 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 9 mins  
3706 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins  
3725 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 mins Self Adhesive  
3726 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins Self Adhesive  
3727 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3760 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 min  
5006 - Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins  
5017 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins

**0724995LCPIETHYOXIND95**

2563 - BX250 Multi Variable Ethylene Oxide Sterilization Indicator

**0724995LCPISTEAMINDZK**

2551 - Multi Variable MVI Steam Sterilization Indicator

**0724995LCPIBROWNESMIND9**

3100 - Browne Steam Integrating Indicator Type 5  
3101 - Browne Steam Integrating Indicator Type 5  
3789-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm

**0724995LCPIVHPINDEC**

2501 - Multi Variable VAPOUR STRIP Multi-Variable Indicator for Vaporised Hydrogen Peroxide

**0724995LCPIGAMMARADINQT**

3301 - Process Gamma Check Indicator Spots

**0724995LCPIFORMHYDINDBK**

2401 - Multi-Variable Formaldehyde Multi-Variable Control Indicator

**Gyártó neve és címe:** Albert Browne Ltd  
Chancery House  
Rayns Way  
Watermead Business Park  
Syston  
Leicester  
LE7 1PF  
UK

**Gyártó egyedi regisztrációs száma (SRN)** GB-MF-000017372

**Meghatalmazott képviselő neve és címe:** STERIS Ireland Ltd  
IDA Business and Technology Park  
Tullamore  
County Offaly  
R35 X865  
Ireland

**Meghatalmazott képviselő egyedi regisztrációs száma:** IE-AR-000010065

**Alapvető egyedi eszközazonosító (UDI-DI):** Az alapvető UDI-DI részleteket lásd a jelen nyilatkozat következő oldalán.

**Termék:** Folyamatindikátorok tartománya  
A termék részleteit lásd a jelen nyilatkozat következő oldalán.

**Rendeltetés:** A folyamatindikátorok termékcsaládot úgy tervezték, hogy színváltozással vagy egyéb fizikai változással jelezze, hogy töltetet alávetették-e a sterilizálási folyamatnak. Ezeket az indikátorokat általában a sterilizálandó tálcába, csomagolásba vagy tasakba helyezik az arról való meggyőződés érdekében, hogy a sterilizálási feltételek teljesültek, illetve a tálca, a csomagolás vagy a tasak külsejére, hogy a feldolgozott és a feldolgozatlan tételek egy pillantással azonosíthatók legyenek. A folyamatindikátorok öntapadós címkék formájában is elérhetők.  
A folyamatindikátorok termékcsalád a következő altermékcsaládokat tartalmazza:  
1] Elpárologtatott hidrogén-peroxid indikátorok  
2] Gőzindikátorok  
3] Etilén-oxid indikátorok  
4] Formaldehid indikátorok  
5] Percetsav folyékony kémiai sterilizáló indikátorok  
6] Gamma-sugárzás indikátorok  
7] Szárazhő-indikátorok

**Besorolás:** I. osztályú nem steril, nem mérő, nem újrahasznosítható eszközök, a VIII. Melléklet 1 szabályának megfelelően

**A használt általános műszaki jellemzők:** N/A

**ISO 13485 tanúsítvány(ok) száma:** MD 504862

**CE jelölés kezdete:** 2019-01-10

**Kiadás helye:** Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.

**Kiadás dátuma:** 2025-06-10

**Átdolgozás:** 36

Ezúton kijelentjük, hogy ezt a megfelelőségi nyilatkozatot a Gyártó kizárólagos felelőssége alapján adják ki, és hogy a fent említett termék(ek) megfelel(nek) az (EU) 2017/745 orvostechikai eszközökről (MDR) szóló RENDELETNEK, amely módosítja a 2001/83/EK irányelvet, a 178/2002/EK és az 1223/2009/EK rendeletet, valamint hatályon kívül helyezi a 90/385/EK és a 93/42/EK tanácsi irányelveket. A terméket az EU MDR szerinti megfelelőségértékelési eljárásnak vetik alá. Minden igazoló dokumentációt a gyártó telephelyén tárolnak.

Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK nevében és részéről aláíró személy- Lásd az alábbi aláírási oldal.

**Termék &  
Alapvető egyedi  
eszközaazonosító  
(UDI-DI):****0724995LCPITSTCNTRLINTE**

2302 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2317 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2340 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2341 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2342 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2375 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2470 - Emulating Des-Check Low Temperature Disinfection Indicator 93°C / 10min  
2471 - Emulating Des-Check Low Temperature Disinfection Indicator 90°C / 5min  
3103 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3104 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins Self-adhesive  
3105 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins Self-adhesive  
3107 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins Self-adhesive  
3108 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins Self-adhesive  
3702 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 9 mins  
3706 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins  
3725 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 mins  
Self Adhesive  
3726 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
Self Adhesive  
3727 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3760 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 min  
5006 - Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins  
5017 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins

**0724995LCVERIFYVHPINDNW**

PCC057 - Verify® HPI Vaporized VH202 Process Indicator Adhesive Label  
PCC062 - Verify® HPI Chemical Indicator

**0724995LCCELERITYHPCIST**

PCC075 - Celerity™ HP Chemical Indicator / Indicador Quimico HP  
PCC078 - Celerity™ Vaporized VH202 Process Indicator Adhesive Label / Etiqueta Adhesiva  
Indicadora De Proceso Vaporized VH202  
PCC079 - Celerity™ HP Multivariable Chemical Indicator / Indicador Quimico Multivariable HP

**0724995LCPISTEAMINDZK**

2551 - Multi Variable MVI Steam Sterilization Indicator

**0724995LCPIVHPINDEC**

2501 - Multi Variable VAPOUR STRIP Multi-Variable Indicator for Vaporised Hydrogen Peroxide

**0724995LCPIBROWNESMIND9**

3100 - Browne Steam Integrating Indicator Type 5  
3101 - Browne Steam Integrating Indicator Type 5  
3789-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm

**0724995LCPICNTRLTUBE6K**

7301 - Sterilizer Control Tubes Type 1 (Black Spot) 121 °C / 15 min  
7302 - Sterilizer Control Tubes Type 2 (Yellow Spot) 134 °C / 3 min  
7303 - Sterilizer Control Tubes Type 3 (Green Spot) 160 °C / 60 min  
7304 - Sterilizer Control Tubes Type 4 (Blue Spot) 180 °C / 12 min  
7305 - Sterilizer Control Tubes Type 5 (White Spot) 160 °C / 120 min, 170 °C / 65 min, 180 °C / 35 min

**0724995LCPIGAMMARADINQT**

3301 - Process Gamma Check Indicator Spots

**0724995LCPIFORMHYDINDBK**

2401 - Multi-Variable Formaldehyde Multi-Variable Control Indicator

<b>Nome e indirizzo del fabbricante:</b>	Albert Browne Ltd Chancery House Rayns Way Watermead Business Park Syston Leicester LE7 1PF UK
<b>Numero unico di registrazione (SRN) del Fabbricante:</b>	GB-MF-000017372
<b>Nome e indirizzo del Rappresentante autorizzato:</b>	STERIS Ireland Ltd IDA Business and Technology Park Tullamore County Offaly R35 X865 Ireland
<b>SRN del Rappresentante autorizzato:</b>	IE-AR-000010065
<b>UDI-DI di base:</b>	Vedere la pagina successiva di questa dichiarazione per dettagli riguardanti l'UDI-DI di base.
<b>Prodotto:</b>	Process Indicators Range Vedere la pagina successiva di questa dichiarazione per dettagli sul prodotto.
<b>Destinazione d'uso:</b>	<p>La linea di indicatori di processo è concepita per indicare se un carico è stato sottoposto a un processo di sterilizzazione tramite una variazione di colore o un'altra alterazione fisica. Questi indicatori sono solitamente posizionati all'interno del vassoio, della confezione o della busta da sterilizzare per fornire la garanzia che le condizioni di sterilizzazione siano state soddisfatte, oppure sono collocati sull'esterno del vassoio, della confezione o della busta, in modo da poter identificare a colpo d'occhio gli articoli trattati da quelli non trattati. Gli indicatori di processo sono disponibili anche sotto forma di etichette autoadesive.</p> <p>La linea di indicatori di processo comprende le seguenti sottocategorie:</p> <ol style="list-style-type: none"><li>1] Indicatori di perossido di idrogeno vaporizzato</li><li>2] Indicatori di vapore</li><li>3] Indicatori di ossido di etilene</li><li>4] Indicatori di formaldeide</li><li>5] Indicatori di sterilizzante chimico liquido a base di acido peracetico</li><li>6] Indicatori di radiazioni gamma</li><li>7] Indicatori di calore secco</li></ol>
<b>Classificazione:</b>	Dispositivi di Classe I non sterili, non di misurazione, non riutilizzabili ai sensi della norma 1 dell'Allegato VIII
<b>Specifiche comuni utilizzate:</b>	N/A
<b>Certificazione ISO 13485 n.:</b>	MD 504862
<b>Inizio della marcatura CE:</b>	2019-01-10
<b>Luogo di emissione:</b>	Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
<b>Data di emissione:</b>	2025-06-10
<b>Revisione:</b>	36



## Dichiarazione Di Conformità



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Si dichiara che la presente Dichiarazione di conformità è rilasciata sotto la responsabilità esclusiva del Fabbricante e che i prodotti sopra menzionati soddisfano le disposizioni del REGOLAMENTO (UE) 2017/745 Dispositivi medici (MDR) che modifica la Direttiva 2001/83/CE, Regolamento (CE) n. 178/2002 e Regolamento (CE) n. 1223/2009 e che abroga le Direttive del Consiglio 90/385/CEE e 93/42/CEE. Il prodotto è oggetto di procedure di valutazione di conformità secondo il Regolamento MDR dell'Unione Europea. Tutta la documentazione di corredo è conservata nei locali del fabbricante.

Firmato in nome e per conto di Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK - Vedere la pagina delle firme di seguito.



**Prodotto & UDI-DI di base:** **0724995LCPIETHYOXIND95**  
2420 Ethylene Oxide Integrating Indicator  
2421 - Process Ethylene Oxide Indicator Spots  
2563 - BX250 Multi Variable Ethylene Oxide Sterilization Indicator

**0724995LCPIFORMHYDINDBK**  
2401 - Multi-Variable Formaldehyde Multi-Variable Control Indicator  
2402 - Process Formaldehyde Indicator Spots

**0724995LCVERFYPERACIDK4**  
LCC015 - Celerity™ Chemical Indicator for enspire™ CLCSPS  
LCC023 - Verify® Chemical Indicator for SYSTEM 1 EXPRESS/PLUS using S40™ Sterilant Concentrate  
PCC029 - Verify® Process Indicator for Reliance™ EPS Endoscope Processing System

**0724995LCPISTEAMINDZK**  
2551 - Multi Variable MVI Steam Sterilization Indicator

**0724995LCPITSTCNTRLINTE**  
2302 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2317 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2340 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2341 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2342 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2375 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2470 - Emulating Des-Check Low Temperature Disinfection Indicator 93°C / 10min  
2471 - Emulating Des-Check Low Temperature Disinfection Indicator 90°C / 5min  
3103 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3104 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins Self-adhesive  
3105 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins Self-adhesive  
3107 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins Self-adhesive  
3108 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins Self-adhesive  
3702 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 9 mins  
3706 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins  
3725 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 mins Self Adhesive  
3726 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins Self Adhesive  
3727 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3737 - Emulating TST Control™ Spot with Sterilizer Record Book 121 °C / 15 mins  
3739 - Emulating TST Control™ Spot with Sterilizer Record Book 134 °C / 3.5 mins  
3760 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 min  
5006 - Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins  
5017 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins

**0724995LCPICNTRLTUBE6K**  
7301 - Sterilizer Control Tubes Type 1 (Black Spot) 121 °C / 15 min  
7302 - Sterilizer Control Tubes Type 2 (Yellow Spot) 134 °C / 3 min  
7303 - Sterilizer Control Tubes Type 3 (Green Spot) 160 °C / 60 min  
7304 - Sterilizer Control Tubes Type 4 (Blue Spot) 180 °C / 12 min  
7305 - Sterilizer Control Tubes Type 5 (White Spot) 160 °C / 120 min, 170 °C / 65 min, 180 °C / 35 min

**0724995LCPIVHPINDEC**  
2501 - Multi Variable VAPOUR STRIP Multi-Variable Indicator for Vaporised Hydrogen Peroxide

**0724995LCVERIFYVHPINDNW**  
PCC057 - Verify® HPI Vaporized VH202 Process Indicator Adhesive Label  
PCC062 - Verify® HPI Chemical Indicator



## Dichiarazione Di Conformità



it

**Prodotto** **0724995LCCELERITYHPCIST**  
**& UDI-DI** PCC075 - Celerity™ HP Chemical Indicator / Indicador Quimico HP  
**di base:** PCC078 - Celerity™ Vaporized VH202 Process Indicator Adhesive Label / Etiqueta Adhesiva Indicadora De Proceso Vaporized VH202  
PCC079 - Celerity™ HP Multivariable Chemical Indicator / Indicador Quimico Multivariable HP

**0724995LCPIBROWNESMIND9**

3100 - Browne Steam Integrating Indicator Type 5  
3101 - Browne Steam Integrating Indicator Type 5  
3785-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm - Italian  
3789-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm

**0724995LCPIGAMMARADINQT**

3301 - Process Gamma Check Indicator Spots

**Gamintojo pavadinimas ir adresas:** Albert Browne Ltd  
Chancery House  
Rayns Way  
Watermead Business Park  
Syston  
Leicester  
LE7 1PF  
UK

**Gamintojo unikalusis registracijos numeris (SRN):** GB-MF-000017372

**Igaliotojo atstovo pavadinimas ir adresas:** STERIS Ireland Ltd  
IDA Business and Technology Park  
Tullamore  
County Offaly  
R35 X865  
Ireland

**Igaliotojo atstovo SRN:** IE-AR-000010065

**Bazinis UDI-DI:** Pagrindinę UDI-DI informaciją rasite kitame šios deklaracijos puslapyje.

**Gaminys:** Proceso indikatorių grupė  
Išsamią informaciją apie gaminį rasite kitame šios deklaracijos puslapyje.

**Numatytoji paskirtis:** Proceso indikatorių grupė skirta parodyti, ar sterilizavimo proceso metu įkrova buvo apdorota – keičiant spalvą ar kitais fiziniais pokyčiais. Paprastai šie indikatoriai dedami į sterilizuojamą padėklą, pakuotę ar maišelį, kad būtų užtikrinta, jog patenkintos sterilizavimo sąlygos, arba dėklo, pakuotės ar maišelio išorėje, kad būtų galima iš pirmo žvilgsnio atpažinti apdorotus ir neapdorotus objektus. Proceso indikatoriai taip pat gali būti lipnių etikečių pavidalo.  
Proceso indikatorių grupę sudaro šie pogrupiai:  
1] Vandenilio peroksido plazmos indikatoriai  
2] Garų indikatoriai  
3] Etileno oksido indikatoriai  
4] Formaldehido indikatoriai  
5] Peroksiacto rūgšties skystos cheminės sterilizavimo medžiagos indikatoriai  
6] Gama spinduliuotės indikatoriai  
7] Sauso karščio indikatoriai

**Klasifikacija:** Klasė I klasės nesterilios, vienkartinės, neturinčios matavimo funkcijos priemonės, remiantis VIII priedo 1 taisykle

**Naudojamos bendrosios specifikacijos:** N/A

**ISO 13485 sertifikato (-ų) nr.:** MD 504862

**CE ženklavimo galiojimo pradžia:** 2019-01-10

**Išdavimo vieta:** Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.

**Išdavimo data:** 2025-06-10

**Redakcija:** 36



## ATITIKTIES DEKLARACIJA



It

Mes deklaruojame, kad ši atitikties deklaracija išduota tik Gamintojo išimtinė atsakomybe ir kad pirmiau nurodytas (-i) gaminys (-iai) atitinka Reglamento (ES) 2017/745 dėl medicinos priemonių, kuriuo iš dalies keičiama Direktyva 2001/83/EB, Reglamentas (EB) Nr. 178/2002 ir Reglamentas (EB) Nr. 1223/2009 ir kuriuo panaikinamos Tarybos direktyvos 90/385/EEB ir 93/42/EEB, nuostatas. Atliktos gaminio atitikties vertinimo procedūros, kaip nurodyta ES Reglamente dėl medicinos priemonių. Visa patvirtinamoji dokumentacija saugoma gamintojo patalpose.

Pasirašyta Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK vardu – žr. pasirašymo puslapį toliau.

**Gaminys 0724995LCPITSTCNTRLINTE**

- & Bazinis** 2302 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2317 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins
- UDI-DI:** 2340 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2341 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2342 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2375 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2470 - Emulating Des-Check Low Temperature Disinfection Indicator 93°C / 10min  
2471 - Emulating Des-Check Low Temperature Disinfection Indicator 90°C / 5min  
3103 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3104 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins Self-adhesive  
3105 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins Self-adhesive  
3107 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins Self-adhesive  
3108 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins Self-adhesive  
3702 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 9 mins  
3706 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins  
3725 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 mins  
Self Adhesive  
3726 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
Self Adhesive  
3727 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3760 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 min  
5006 - Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins  
5017 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins

**0724995LCPISTEAMINDZK**

- 2551 - Multi Variable MVI Steam Sterilization Indicator

**0724995LCPIVHPINDEC**

- 2501 - Multi Variable VAPOUR STRIP Multi-Variable Indicator for Vaporised Hydrogen Peroxide

**0724995LCCELERITYHPCIST**

- PCC075 - Celerity™ HP Chemical Indicator / Indicador Quimico HP  
PCC079 - Celerity™ HP Multivariable Chemical Indicator / Indicador Quimico Multivariable HP

**0724995LCPIBROWNESMIND9**

- 3100 - Browne Steam Integrating Indicator Type 5  
3101 - Browne Steam Integrating Indicator Type 5  
3789-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm

**0724995LCPIGAMMARADINQT**

- 3301 - Process Gamma Check Indicator Spots

**0724995LCPIFORMHYDINDBK**

- 2401 - Multi-Variable Formaldehyde Multi-Variable Control Indicator

<b>Ražotāja nosaukums un adrese:</b>	Albert Browne Ltd Chancery House Rayns Way Watermead Business Park Syston Leicester LE7 1PF UK
<b>Ražotāja vienotais reģistrācijas numurs (Single Registration Number – SRN):</b>	GB-MF-000017372
<b>Pilnvarotā pārstāvja nosaukums un adrese:</b>	STERIS Ireland Ltd IDA Business and Technology Park Tullamore County Offaly R35 X865 Ireland
<b>Pilnvarotā pārstāvja SRN:</b>	IE-AR-000010065
<b>Pamata UDI-DI:</b>	UDI-DI pamatinformāciju skatiet šīs deklarācijas nākamajā lapā.
<b>Izstrādājums:</b>	Procesa indikatoru klāsts Sīkāku informāciju par produktu skatiet šīs deklarācijas nākamajā lapā.
<b>Paredzētais nolūks:</b>	Procesa indikatoru klāsts ir paredzēts, lai, mainot krāsu vai veicot citas fiziskas izmaiņas, norādītu, vai komplekts ir apstrādāts sterilizācijas procesā. Šie indikatori parasti tiek ievietoti sterilizējamajā paplātē, iepakojumā vai maisiņā, lai nodrošinātu sterilizācijas nosacījumu izpildi, vai paplātes, iepakojuma vai maisiņa ārpusē, lai varētu ātri identificēt apstrādātos un neapstrādātos priekšmetus. Procesa indikatori var būt arī pašlīmējošu etiķešu veidā. Procesa indikatoru klāsta apakšgrupas: 1] iztvaicēta ūdeņraža peroksīda indikatori; 2] tvaika indikatori; 3] etilēnoksīda indikatori; 4] formaldehīda indikatori; 5] peroksietilēnskābes šķidrā ķīmiskā sterilizatora indikatori; 6] gamma starojuma indikatori; 7] sausā siltuma indikatori;
<b>Klasifikācija:</b>	I klases nesterilas, mērīšanai neparedzētas, atkārtoti nelietojamās ierīces saskaņā ar VIII pielikuma 1. Noteikumu
<b>Izmantotās kopējās specifikācijas:</b>	N/A
<b>ISO 13485 sertifikāta vai sertifikātu Nr.:</b>	MD 504862
<b>CE zīmes piešķiršanas datums:</b>	2019-01-10
<b>Izdošanas vieta:</b>	Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK
<b>Izdošanas datums:</b>	2025-06-10
<b>Versija:</b>	36

Ar šo paziņojam, ka šī atbilstības deklarācija ir izdota vienīgi uz ražotāja atbildību un ka iepriekš minētais izstrādājums vai izstrādājumi atbilst šajā regulā izklāstītajiem noteikumiem: REGULA (ES) 2017/745, kas attiecas uz medicīniskām ierīcēm (Medicīnisko ierīču regula), ar ko groza Direktīvu 2001/83/EK, Regulu (EK) Nr. 178/2002 un Regulu (EK) Nr. 1223/2009 un atceļ Padomes Direktīvas 90/385/EK un 93/42/EEK. Izstrādājumam ir veiktas atbilstības novērtēšanas procedūras saskaņā ar ES Medicīnisko ierīču regulu. Visi apliecinātie dokumenti ir saglabāti ražotāja objektos.

Parakstīts Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK vārdā — skatīt paraksta lapu tālāk.

- Izstrādājums & Pamata UDI-DI:** **0724995LCPITSTCNTRLINTE**  
2302 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2317 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2340 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2341 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2342 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2375 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2470 - Emulating Des-Check Low Temperature Disinfection Indicator 93°C / 10min  
2471 - Emulating Des-Check Low Temperature Disinfection Indicator 90°C / 5min  
3103 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3104 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins Self-adhesive  
3105 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins Self-adhesive  
3107 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins Self-adhesive  
3108 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins Self-adhesive  
3702 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 9 mins  
3706 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins  
3725 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 mins Self Adhesive  
3726 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins Self Adhesive  
3727 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3760 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 min  
5006 - Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins  
5017 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins
- 0724995LCPISTEAMINDZK**  
2551 - Multi Variable MVI Steam Sterilization Indicator
- 0724995LCPIETHYOXIND95**  
2420 - Ethylene Oxide Integrating Indicator
- 0724995LCPIBROWNESMIND9**  
3100 - Browne Steam Integrating Indicator Type 5  
3101 - Browne Steam Integrating Indicator Type 5  
3789-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm
- 0724995LCCELERITYHPCIST**  
PCC075 - Celerity™ HP Chemical Indicator / Indicador Quimico HP  
PCC079 - Celerity™ HP Multivariable Chemical Indicator / Indicador Quimico Multivariable HP
- 0724995LCPIETHYOXIND95**  
2421 - Process Ethylene Oxide Indicator Spots
- 0724995LCPIVHPINDEC**  
2501 - Multi Variable VAPOUR STRIP Multi-Variable Indicator for Vaporised Hydrogen Peroxide
- 0724995LCPICNTRLTUBE6K**  
7301 - Sterilizer Control Tubes Type 1 (Black Spot) 121 °C / 15 min  
7302 - Sterilizer Control Tubes Type 2 (Yellow Spot) 134 °C / 3 min  
7303 - Sterilizer Control Tubes Type 3 (Green Spot) 160 °C / 60 min  
7304 - Sterilizer Control Tubes Type 4 (Blue Spot) 180 °C / 12 min  
7305 - Sterilizer Control Tubes Type 5 (White Spot) 160 °C / 120 min, 170 °C / 65 min, 180 °C / 35 min
- 0724995LCPIGAMMARADINQT**  
3301 - Process Gamma Check Indicator Spots
- 0724995LCPIFORMHYDINDBK**  
2401 - Multi-Variable Formaldehyde Multi-Variable Control Indicator

<b>Naam en adres van de fabrikant:</b>	Albert Browne Ltd Chancery House Rayns Way46 Watermead Business Park Syston Leicester LE7 1PF UK
<b>Single Registration Number (SRN) van de fabrikant:</b>	GB-MF-000017372
<b>Naam en adres van de bevoegde vertegenwoordiger:</b>	STERIS Ireland Ltd IDA Business and Technology Park Tullamore County Offaly R35 X865 Ireland
<b>Bevoegde vertegenwoordiger SRN:</b>	IE-AR-000010065
<b>Basis-UDI-DI:</b>	Zie de volgende pagina van deze verklaring voor informatie over de Basic UDI-DI.
<b>Product:</b>	Assortiment procesindicatoren Zie de volgende pagina van deze verklaring voor productdetails.
<b>Beoogd doel:</b>	Het assortiment procesindicatoren is ontworpen om door middel van een kleurverandering of een andere fysieke verandering aan te geven of een lading door een sterilisatieproces is verwerkt. Deze indicatoren worden doorgaans in de te steriliseren tray, verpakking of zak geplaatst om er zeker van te zijn dat aan de sterilisatievoorwaarden is voldaan, of aan de buitenkant van de tray, verpakking of zak, zodat de verwerkte en niet-verwerkte items in een oogopslag kunnen worden geïdentificeerd. Procesindicatoren kunnen ook de vorm hebben van zelfklevende labels. Het assortiment procesindicatoren bevat de volgende subassortimenten: 1] Indicatoren voor verdampte waterstofperoxide 2] Stoomindicatoren 3] Indicatoren voor ethyleenoxide 4] Indicatoren voor formaldehyde 5] Indicatoren voor vloeibare chemische sterilisatiemiddelen met perazijnzuur 6] Indicatoren voor gammastraling 7] Indicatoren voor droge hitte
<b>Classificatie:</b>	Klasse I niet steriele, niet metende, niet herbruikbare hulpmiddelen conform voorschrift 1 van Bijlage VIII
<b>Gebruikte gemeenschappelijke specificaties:</b>	N/A
<b>ISO 13485-certificaat/certificaten nr.:</b>	MD 504862
<b>Ingangsdatum CE-markering:</b>	2019-01-10
<b>Plaats van uitgifte:</b>	Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK
<b>Datum van uitgifte:</b>	2025-06-10
<b>Revisie:</b>	36

Hiermee verklaren we dat deze conformiteitsverklaring onder de uitsluitende verantwoordelijkheid van de Producent wordt verstrekt en dat bovengenoemd(e) product(en) voldoet(n) aan de bepalingen van EU-VERORDENING 2017/745 voor Medische hulpmiddelen (MDR) en houdende wijziging van Richtlijn 2001/83/EG, Verordening (EG) nr. 178/2002 en Verordening (EG) nr. 1223/2009 en tot intrekking van Richtlijnen 90/385/EEG en 93/42/EEG van de Raad. Het product is onderworpen aan conformiteitsbeoordelingsprocedures conform EU MDR. Alle bijbehorende documentatie wordt in het bedrijfspand van de producent bewaard.

Ondertekend voor en namens Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK - Zie onderstaande handtekeningpagina.

**Product 0724995LCPITSTCNTRLINTE**

**& Basic** 2302 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
**UDI-DI:** 2317 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2340 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2341 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2342 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2375 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
3103 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3104 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins Self-adhesive  
3105 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins Self-adhesive  
3107 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins Self-adhesive  
3108 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins Self-adhesive  
3702 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 9 mins  
3706 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins  
3725 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 mins Self Adhesive  
3726 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins Self Adhesive  
3727 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3737 - Emulating TST Control™ Spot with Sterilizer Record Book 121 °C / 15 mins  
3739 - Emulating TST Control™ Spot with Sterilizer Record Book 134 °C / 3.5 mins  
3760 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 min  
5006 - Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins  
5017 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins

**0724995LCVERIFYVHPINDNW**

PCC057 - Verify® HPI Vaporized VH202 Process Indicator Adhesive Label  
PCC062 - Verify® HPI Chemical Indicator

**0724995LCCELERITYHPCIST**

PCC075 - Celerity™ HP Chemical Indicator / Indicador Quimico HP  
PCC078 - Celerity™ Vaporized VH202 Process Indicator Adhesive Label / Etiqueta Adhesiva Indicadora De Proceso Vaporized VH202  
PCC079 - Celerity™ HP Multivariable Chemical Indicator / Indicador Quimico Multivariable HP

**0724995LCPISTEAMINDZK**

2551 - Multi Variable MVI Steam Sterilization Indicator

**0724995LCPIBROWNESMIND9**

3100 - Browne Steam Integrating Indicator Type 5  
3101 - Browne Steam Integrating Indicator Type 5  
3789-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm

**0724995LCPIVHPINDEC**

2501 - Multi Variable VAPOUR STRIP Multi-Variable Indicator for Vaporised Hydrogen Peroxide

**0724995LCPICNTRLTUBE6K**

7301 - Sterilizer Control Tubes Type 1 (Black Spot) 121 °C / 15 min  
7302 - Sterilizer Control Tubes Type 2 (Yellow Spot) 134 °C / 3 min  
7303 - Sterilizer Control Tubes Type 3 (Green Spot) 160 °C / 60 min  
7304 - Sterilizer Control Tubes Type 4 (Blue Spot) 180 °C / 12 min  
7305 - Sterilizer Control Tubes Type 5 (White Spot) 160 °C / 120 min, 170 °C / 65 min, 180 °C / 35 min

**0724995LCPIGAMMARADINQT**

3301 - Process Gamma Check Indicator Spots

**0724995LCPIFORMHYDINDBK**

2401 - Multi-Variable Formaldehyde Multi-Variable Control Indicator

<b>Nazwa i adres producenta:</b>	Albert Browne Ltd Chancery House Rayns Way Watermead Business Park Syston Leicester LE7 1PF UK
<b>Indywidualny numer rejestracyjny (SRN) producenta</b>	GB-MF-000017372
<b>Nazwa i adres autoryzowanego przedstawiciela:</b>	STERIS Ireland Ltd IDA Business and Technology Park Tullamore County Offaly R35 X865 Ireland
<b>Indywidualny numer rejestracyjny (SRN) autoryzowanego przedstawiciela:</b>	IE-AR-000010065
<b>Kod UDI-DI:</b>	Podstawowe informacje dotyczące UDI-DI znajdują się na następnej stronie niniejszej deklaracji.
<b>Produkt:</b>	Asortyment wskaźników Process Indicators Szczegóły produktu znajdują się na następnej stronie niniejszej deklaracji.
<b>Przeznaczenie:</b>	Asortyment urządzeń testowych (wskaźników) Process Indicators został zaprojektowany tak, by wskazywał, czy wsad został należycie wysterylizowany poprzez zmianę barwy lub zmianę innych cech fizycznych. Wskaźniki te są zazwyczaj umieszczane wewnątrz kuwety, pakietu lub torebki do sterylizacji w celu zapewnienia, że warunki sterylizacji zostały spełnione, lub też na zewnątrz kuwety, pakietu lub torebki, by można było łatwo rozpoznać elementy już poddane i jeszcze nie poddane sterylizacji. Wskaźniki mogą również mieć formę samoprzylepnych etykiet. Asortyment wskaźników Process Indicators obejmuje następujące podgrupy: 1] Wskaźniki dla odparowanego nadtlenku wodoru 2] Wskaźniki dla pary 3] Wskaźnik dla tlenu etylenu 4] Wskaźniki dla formaldehydu 5] Wskaźniki dla chemicznego środka sterylizującego w postaci płynnego kwasu nadoctowego 6] Wskaźniki dla promieniowania gamma 7] Wskaźniki dla ciepła suchego
<b>Klasyfikacja:</b>	Klasa I, wyroby niesterylne, bez funkcji pomiarowej, nienadające się do ponownego użytku, zgodnie z regułą 1 z Załącznika VIII
<b>Użyte wspólne specyfikacje:</b>	N/A
<b>Nr certyfikatu(-ów) ISO 13485:</b>	MD 504862
<b>Początek obowiązywania oznaczenia CE:</b>	2019-01-10
<b>Miejsce wydania:</b>	Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
<b>Data wydania:</b>	2025-06-10
<b>Wersja:</b>	36



## Deklaracja Zgodności



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Oświadczamy, że niniejsza deklaracja zgodności zostaje wydana na wyłączną odpowiedzialność Producenta, oraz że wyżej wymieniony(-e) produkt(y) spełnia(ją) wymagania ROZPORZĄDZENIA (UE) 2017/745 w sprawie wyrobów medycznych (MDR), zmiany dyrektywy 2001/83/WE, rozporządzenia (WE) nr 178/2002 i rozporządzenia (WE) nr 1223/2009 oraz uchylecia dyrektyw Rady 90/385/EWG i 93/42/EWG. Produkt został poddany procedurom oceny zgodności zgodnie z rozporządzeniem MDR UE. Całość potwierdzającej to dokumentacji jest przechowywana u producenta.

Podpisano dla oraz w imieniu Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK – patrz poniższa strona podpisów.

**Produkt & Basic** 0724995LCPIETHYOXIND95  
2420 - Ethylene Oxide Integrating Indicator  
**UDI-DI:** 2421 - Process Ethylene Oxide Indicator Spots  
2563 - BX250 Multi Variable Ethylene Oxide Sterilization Indicator

**0724995LCPIFORMHYDINDBK**

2401 - Multi-Variable Formaldehyde Multi-Variable Control Indicator  
2402 - Process Formaldehyde Indicator Spots

**Steam indicators - 0724995LCPITSTCNTRLINTE**

2302 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2317 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2340 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2341 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2342 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2375 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2470 - Emulating Des-Check Low Temperature Disinfection Indicator 93°C / 10min  
2471 - Emulating Des-Check Low Temperature Disinfection Indicator 90°C / 5min  
3103 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3104 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins Self-adhesive  
3105 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins Self-adhesive  
3107 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins Self-adhesive  
3108 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins Self-adhesive  
3702 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 9 mins  
3706 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins  
3725 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 mins  
Self Adhesive  
3726 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
Self Adhesive  
3727 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3760 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 min  
5006 - Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins  
5017 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins

**0724995LCPICNTRLTUBE6K**

7301 - Sterilizer Control Tubes Type 1 (Black Spot) 121 °C / 15 min  
7302 - Sterilizer Control Tubes Type 2 (Yellow Spot) 134 °C / 3 min  
7303 - Sterilizer Control Tubes Type 3 (Green Spot) 160 °C / 60 min  
7304 - Sterilizer Control Tubes Type 4 (Blue Spot) 180 °C / 12 min  
7305 - Sterilizer Control Tubes Type 5 (White Spot) 160 °C / 120 min, 170 °C / 65 min, 180 °C / 35 min

**0724995LCPIVHPINDEC**

2501 - Multi Variable VAPOUR STRIP Multi-Variable Indicator for Vaporised Hydrogen Peroxide

**0724995LCVERIFYVHPINDNW**

PCC057 - Verify® HPI Vaporized VH202 Process Indicator Adhesive Label  
PCC062 - Verify® HPI Chemical Indicator

**0724995LCCELERITYHPCIST**

PCC075 - Celerity™ HP Chemical Indicator / Indicador Quimico HP  
PCC078 - Celerity™ Vaporized VH202 Process Indicator Adhesive Label / Etiqueta Adhesiva Indicadora De Proceso Vaporized VH202  
PCC079 - Celerity™ HP Multivariable Chemical Indicator / Indicador Quimico Multivariable HP

**0724995LCPISTEAMINDZK**

2551 - Multi Variable MVI Steam Sterilization Indicator

**0724995LCPIBROWNESMIND9**

3100 - Browne Steam Integrating Indicator Type 5  
3101 - Browne Steam Integrating Indicator Type 5  
3789-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm

**0724995LCPIGAMMARADINQT**

3301 - Process Gamma Check Indicator Spots

<b>Nome e morada do Fabricante:</b>	Albert Browne Ltd Chancery House Rayns Way Watermead Business Park Syston Leicester LE7 1PF UK
<b>Número de Registo Único (NRU) do Fabricante</b>	GB-MF-000017372
<b>Nome e morada do Representante Autorizado</b>	STERIS Ireland Ltd IDA Business and Technology Park Tullamore County Offaly R35 X865 Ireland
<b>NRU Representante Autorizado:</b>	IE-AR-000010065
<b>UDI-DI básico:</b>	Consulte a página seguinte da presente declaração para detalhes do Basic UDI-DI.
<b>Produto:</b>	Gama de Indicadores de Processo Para mais informações sobre o produto, consulte a página seguinte da presente declaração.
<b>Finalidade pretendida:</b>	<p>A Gama de Indicadores de Processo foi concebida para indicar se uma carga foi processada através de um processo de esterilização por meio de alteração de cor ou de outra alteração física. Estes indicadores são normalmente colocados ou no interior da bandeja, da embalagem ou da bolsa a esterilizar, para garantir que as condições de esterilização foram cumpridas, ou no exterior da bandeja, da embalagem ou da bolsa, para que os artigos processados e não processados possam ser identificados num relance. Os indicadores de processo podem também ter a forma de etiquetas autocolantes.</p> <p>A Gama de Indicadores de Processo contém as seguintes sub-gamas:</p> <ol style="list-style-type: none"><li>1] Indicadores de peróxido de hidrogénio vaporizado</li><li>2] Indicadores de vapor</li><li>3] Indicadores de óxido de etileno</li><li>4] Indicadores de formaldeído</li><li>5] Indicadores de químicos esterilizantes líquidos de ácido peracético</li><li>6] Indicadores de radiação gama</li><li>7] Indicadores de calor seco</li></ol>
<b>Classificação:</b>	Dispositivos de Classe I não-estéril, sem medição, não reutilizáveis, de acordo com a Regra 1 do Anexo VIII
<b>Especificações comuns utilizadas:</b>	N/A
<b>Certificado(s) ISO 13485 n.º:</b>	MD 504862
<b>Início da marcação CE:</b>	2019-01-10
<b>Local de emissão:</b>	Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
<b>Data de emissão:</b>	2025-06-10
<b>Revisão:</b>	36



## Declaração De Conformidade



pt

Declaramos pelo presente documento que esta declaração de conformidade é emitida sob a responsabilidade exclusiva do Fabricante e que os produtos supramencionados cumprem as disposições do Regulamento (UE) 2017/745 sobre Dispositivos Médicos (RDM) que modifica a Diretiva 2001/83/CE, o Regulamento (CE) n.º 178/2002 e o Regulamento (CE) n.º 1223/2009, revogando as Diretivas do Conselho 90/385/CEE e 93/42/CEE. O produto foi sujeito a procedimentos de avaliação da conformidade, de acordo com o Regulamento de Dispositivos Médicos da União Europeia. Toda a documentação de apoio é conservada nas instalações do fabricante.

Assinado por e em nome de Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK - Ver página de assinatura em baixo.

**Produto** **0724995LCPIETHYOXIND95**  
& **UDI-** 2421 - Process Ethylene Oxide Indicator Spots  
**DI** 2563 - BX250 Multi Variable Ethylene Oxide Sterilization Indicator  
**básico:**

**0724995LCPIFORMHYDINDBK**  
2401 - Multi-Variable Formaldehyde Multi-Variable Control Indicator  
2402 - Process Formaldehyde Indicator Spots

**0724995LCVERFYPERACIDK4**  
LCC015 - Celerity™ Chemical Indicator for enspire™ CLCSPS  
LCC023 - Verify® Chemical Indicator for SYSTEM 1 EXPRESS/PLUS using S40™ Sterilant Concentrate

**0724995LCPISTEAMINDZK**  
2551 - Multi Variable MVI Steam Sterilization Indicator

**0724995LCPISTCNTRLINTE**  
2302 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2317 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2340 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2341 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2342 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2375 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2470 - Emulating Des-Check Low Temperature Disinfection Indicator 93°C / 10min  
2471 - Emulating Des-Check Low Temperature Disinfection Indicator 90°C / 5min  
3103 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3104 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins Self-adhesive  
3105 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins Self-adhesive  
3107 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins Self-adhesive  
3108 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins Self-adhesive  
3702 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 9 mins  
3706 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins  
3725 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 mins Self Adhesive  
3726 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins Self Adhesive  
3727 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3760 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 min  
5006 - Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins  
5017 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins

**0724995LCPICNTRLTUBE6K**  
7301 - Sterilizer Control Tubes Type 1 (Black Spot) 121 °C / 15 min  
7302 - Sterilizer Control Tubes Type 2 (Yellow Spot) 134 °C / 3 min  
7303 - Sterilizer Control Tubes Type 3 (Green Spot) 160 °C / 60 min  
7304 - Sterilizer Control Tubes Type 4 (Blue Spot) 180 °C / 12 min  
7305 - Sterilizer Control Tubes Type 5 (White Spot) 160 °C / 120 min, 170 °C / 65 min, 180 °C / 35 min

**0724995LCPIBROWNESMIND9**  
3100 - Browne Steam Integrating Indicator Type 5  
3101 - Browne Steam Integrating Indicator Type 5  
3789-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm  
3794-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm – Portuguese

**0724995LCPIVHPINDEC**  
2501 - Multi Variable VAPOUR STRIP Multi-Variable Indicator for Vaporised Hydrogen Peroxide

**0724995LCVERIFYVHPINDNW**  
PCC044 - Verify® Control Quimico VH202 / Vaporized VH202 Chemical Indicator / Indicador Quimico Vaporizado VH202  
PCC057 - Verify® HPI Vaporized VH202 Process Indicator Adhesive Label



**Produto & UDI-** PCC062 - Verify® HPI Chemical Indicator

**DI** **0724995LCCELERITYHPCIST**

**básico:** PCC075 - Celerity™ HP Chemical Indicator / Indicador Químico HP  
PCC078 - Celerity™ Vaporized VH202 Process Indicator Adhesive Label / Etiqueta Adesiva Indicadora De Processo Vaporized VH202  
PCC079 - Celerity™ HP Multivariable Chemical Indicator / Indicador Químico Multivariable HP

**0724995LCPIVFYSIXCESSTK**

PCC035 - SixCess™ 134C 5.3 Min / 121C 15 Min Indicadores / Indicator / Indicadore

**0724995LCPIGAMMARADINQT**

3301 - Process Gamma Check Indicator Spots

<b>Numele și adresa producătorului:</b>	Albert Browne Ltd Chancery House Rayns Way Watermead Business Park Syston Leicester LE7 1PF UK
<b>Număr unic de înregistrare al producătorului (SRN)</b>	GB-MF-000017372
<b>Numele și adresa reprezentantului autorizat:</b>	STERIS Ireland Ltd IDA Business and Technology Park Tullamore County Offaly R35 X865 Ireland
<b>SRN-ul reprezentantului autorizat:</b>	IE-AR-000010065
<b>UDI-DI de bază:</b>	Consultați pagina următoare a acestei declarații pentru detaliile UDI-DI de bază.
<b>Produs:</b>	Gama de indicatori de proces Consultați pagina următoare a acestei declarații pentru detalii despre produs.
<b>Scopul propus:</b>	Gama de indicatori de proces este concepută pentru a indica dacă o sarcină a fost procesată printr-un proces de sterilizare prin intermediul schimbării culorii sau altă modificare fizică. Acești indicatori sunt plasați, de obicei, fie în interiorul tăvii, pachetului sau pungii care urmează să fie sterilizate, pentru a asigura că au fost îndeplinite condițiile de sterilizare, fie pe partea exterioară a tăvii, pachetului sau pungii, astfel încât elementele prelucrate și neprelucrate să poată fi identificate dintr-o privire. Indicatorii de proces pot fi, de asemenea, sub formă de etichete autoadezive. Gama de indicatori de proces conține următoarele sub-game: 1] Indicatori de peroxid de hidrogen vaporizat 2] Indicatori de abur 3] Integratori de oxid de etilenă 4] Integratori de formaldehidă 5] Indicatori de sterilizare chimică lichidă cu acid peracetic 6] Indicatori de radiații gamma 7] Indicatori de căldură uscată
<b>Clasificare:</b>	Clasa I, dispozitive nesterile, fără funcție de măsurare, nereutilizabile, în conformitate cu regula ___ din Anexa VIII
<b>Specificații generale utilizate:</b>	N/A
<b>ISO 13485</b>	MD 504862
<b>Certificat(e) CE nr.:</b>	
<b>Data de început a marcajului CE:</b>	2019-01-10
<b>Locul emiterii:</b>	Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
<b>Data emiterii:</b>	2025-06-10
<b>Revizia:</b>	36

Declarăm prin prezentul document că această declarație de conformitate este emisă sub responsabilitatea exclusivă a Producătorului și că produsul (produsele) menționat(e) mai sus respectă dispozițiile REGULAMENTULUI (UE) 2017/745 privind dispozitivele medicale (MDR), de modificare a Directivei 2001/83/CE, a Regulamentului (CE) nr. 178/2002 și a Regulamentului (CE) nr. 1223/2009 și de abrogare a Directivelor 90/385/CEE și 93/42/CEE ale Consiliului. Produsul a fost supus procedurilor de evaluare a conformității conform MDR UE. Întreaga documentație justificativă este păstrată la sediul producătorului.

Semnat pentru și în numele Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK - A se vedea pagina de semnături mai jos.

**Produs 0724995LCPITSTCNTRLINTE**

<b>&amp; UDI-</b>	2302 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins
<b>DI de</b>	2317 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins
<b>bază:</b>	2340 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins
	2341 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins
	2342 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins
	2375 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins
	3103 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive
	3104 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins Self-adhesive
	3105 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins Self-adhesive
	3107 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins Self-adhesive
	3108 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins Self-adhesive
	3702 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 9 mins
	3706 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins
	3725 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 mins Self Adhesive
	3726 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins Self Adhesive
	3727 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive
	3760 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 min
	5006 - Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins
	5017 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins

**0724995LCPISTEAMINDZK**

2551 - Multi Variable MVI Steam Sterilization Indicator

**0724995LCPIETHYOXIND95**

2420 - Ethylene Oxide Integrating Indicator

**0724995LCPIVHPINDEC**

2501 - Multi Variable VAPOUR STRIP Multi-Variable Indicator for Vaporised Hydrogen Peroxide

**0724995LCCELERITYHPCIST**

PCC075 - Celerity™ HP Chemical Indicator / Indicador Quimico HP

PCC079 - Celerity™ HP Multivariable Chemical Indicator / Indicador Quimico Multivariable HP

**0724995LCPIBROWNESMIND9**

3100 - Browne Steam Integrating Indicator Type 5

3101 - Browne Steam Integrating Indicator Type 5

3789-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm

**0724995LCPIGAMMARADINQT**

3301 - Process Gamma Check Indicator Spots

**0724995LCPIFORMHYDINDBK**

2401 - Multi-Variable Formaldehyde Multi-Variable Control Indicator

<b>Názov a adresa výrobcu:</b>	Albert Browne Ltd Chancery House Rayns Way Watermead Business Park Syston Leicester LE7 1PF UK
<b>Jedinečné registračné číslo výrobcu (SRN – Single Registration Number)</b>	GB-MF-000017372
<b>Názov a adresa oprávneného zástupcu:</b>	STERIS Ireland Ltd IDA Business and Technology Park Tullamore County Offaly R35 X865 Ireland
<b>SRN oprávneného zástupcu:</b>	IE-AR-000010065
<b>Základný identifikátor UDI-DI:</b>	Základné podrobnosti o UDI-DI nájdete na ďalšej strane tohto vyhlásenia.
<b>Produkt:</b>	Sortiment indikátorov procesu Podrobnosti o produkte nájdete na ďalšej strane tohto vyhlásenia.
<b>Zamýšľaný účel:</b>	Sortiment indikátorov na overenie procesu je navrhnutý tak, aby indikátory indikovali úspešnosť sterilizačného procesu prostredníctvom zmeny farby alebo inej fyzickej zmeny. Tieto indikátory sú zvyčajne umiestnené vnútri zásobníka, balenia alebo vrečka, ktoré sa majú sterilizovať, aby sa zabezpečilo, že boli splnené podmienky sterilizácie. Niektoré sa môžu umiestniť na vonkajšiu stranu zásobníka, balenia alebo vrečka, aby sa dalo na prvý pohľad rozoznať, či boli položky spracované alebo nie. Indikátory procesu môžu mať aj formu samolepiacich štítkov. Sortiment indikátorov procesu obsahuje nasledujúce série: 1] Indikátory odpareného peroxidu vodíka 2] Indikátory pary 3] Indikátory etylénoxidu 4] Indikátory formaldehydu 5] Indikátory kyseliny peroctovej, kvapalného prípravku na chemickú sterilizáciu 6] Indikátory gama žiarenia 7] Indikátory suchého tepla
<b>Klasifikácia:</b>	Trieda I zariadenia nesterilné, bez meracej funkcie, opätovne nepoužiteľné podľa Pravidla 1 Prílohy VIII
<b>Použité spoločné špecifikácie:</b>	N/A
<b>ISO 13485</b>	MD 504862
<b>Certifikát(y) č.:</b>	
<b>Dátum začiatku označovania značkou zhody CE:</b>	2019-01-10
<b>Miesto vydania:</b>	Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
<b>Dátum vydania:</b>	2025-06-10
<b>Revidované vydanie:</b>	36

Týmto vyhlasujeme, že toto Vyhlásenie o zhode sa vydáva na výhradnú zodpovednosť Výrobcu a že vyššie uvedený/-é výrobok/-ky spĺňa/-jú ustanovenia NARIADENIA (EÚ) 2017/745 o zdravotníckych pomôckach (MDR), ktorým sa mení a dopĺňa smernica 2001/83/ES, nariadenie (ES) č. 178/2002 a nariadenie (ES) č. 1223/2009, ktorým sa rušia smernice Rady 90/385/EHS a 93/42/EHS. Na daný výrobok boli aplikované postupy posudzovania zhody podľa nariadenia EÚ o zdravotníckych pomôckach (MDR). Kompletná sprievodná dokumentácia sa nachádza v priestoroch výrobcu.

Podpísané za a v mene Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK – pozrite podpisovú stranu nižšie.

**Výrobok & Základné číslo UDI-DI:** **0724995LCPITSTCNTRLINTE**  
2302 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2317 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2340 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2341 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2342 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2375 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2470 - Emulating Des-Check Low Temperature Disinfection Indicator 93°C / 10min  
2471 - Emulating Des-Check Low Temperature Disinfection Indicator 90°C / 5min  
3103 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3104 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins Self-adhesive  
3105 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins Self-adhesive  
3107 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins Self-adhesive  
3108 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins Self-adhesive  
3702 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 9 mins  
3706 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins  
3725 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 mins Self Adhesive  
3726 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins Self Adhesive  
3727 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3760 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 min  
5006 - Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins  
5017 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins

**0724995LCPISTEAMINDZK**

2551 - Multi Variable MVI Steam Sterilization Indicator

**0724995LCPIFORMHYDINDBK**

2401 - Multi-Variable Formaldehyde Multi-Variable Control Indicator

**0724995LCCELERITYHPCIST**

PCC075 - Celerity™ HP Chemical Indicator / Indicador Quimico HP

**0724995LCPIETHYOXIND95**

2421 - Process Ethylene Oxide Indicator Spots

**0724995LCPIBROWNESMIND9**

3100 - Browne Steam Integrating Indicator Type 5

3101 - Browne Steam Integrating Indicator Type 5

3789-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm

**0724995LCPIVHPINDEC**

2501 - Multi Variable VAPOUR STRIP Multi-Variable Indicator for Vaporised Hydrogen Peroxide

**0724995LCPICNTRLTUBE6K**

7301 - Sterilizer Control Tubes Type 1 (Black Spot) 121 °C / 15 min

7302 - Sterilizer Control Tubes Type 2 (Yellow Spot) 134 °C / 3 min

7303 - Sterilizer Control Tubes Type 3 (Green Spot) 160 °C / 60 min

7304 - Sterilizer Control Tubes Type 4 (Blue Spot) 180 °C / 12 min

7305 - Sterilizer Control Tubes Type 5 (White Spot) 160 °C / 120 min, 170 °C / 65 min, 180 °C / 35 min

**0724995LCPIGAMMARADINQT**

3301 - Process Gamma Check Indicator Spots

<b>Ime in naslov proizvajalca:</b>	Albert Browne Ltd Chancery House Rayns Way Watermead Business Park Syston Leicester LE7 1PF UK
<b>Enotna registrska številka proizvajalca (SRN)</b>	GB-MF-000017372
<b>Ime in naslov pooblaščenega zastopnika:</b>	STERIS Ireland Ltd IDA Business and Technology Park Tullamore County Offaly R35 X865 Ireland
<b>SRN pooblaščenega zastopnika:</b>	IE-AR-000010065
<b>Osnovni UDI-DI:</b>	Za osnovne podrobnosti UDI-DI glejte naslednjo stran te izjave.
<b>Izdelek:</b>	Serija indikatorjev procesa Podrobnosti o izdelku najdete na naslednji strani te izjave.
<b>Predvideni namen:</b>	Serija indikatorjev procesa je zasnovana tako, da s spremembo barve ali drugo fizično spremembo pokaže, ali je bil material obdelan v postopku sterilizacije. Ti indikatorji so običajno nameščeni znotraj pladnja, embalaže ali vrečke, ki se sterilizira, da se zagotovi izpolnjevanje pogojev sterilizacije, ali na zunanji strani pladnja, embalaže ali vrečke, da je mogoče na prvi pogled prepoznati obdelane in neobdelane izdelke. Indikatorji procesa so lahko tudi v obliki samolepilnih nalepk. Serija indikatorjev procesa vsebuje naslednje podserije: 1] Indikatorji uparjenega vodikovega peroksida 2] Parni indikatorji 3] Indikatorji etilen oksida 4] Indikatorji formaldehida 5] Indikatorji tekočega kemičnega sterilizatorja perocetne kisline 6] Indikatorji gama sevanja 7] Indikatorji suhe vročine
<b>Razvrstitev:</b>	Razred I – nesterilni pripomočki brez merilne funkcije in za enkratno uporabo v skladu s pravilo __ Priloge VIII
<b>Uporabljene skupne specifikacije:</b>	N/A
<b>Št. certifikata(-ov) ISO 13485:</b>	MD 504862
<b>Začetek označevanja z oznako CE:</b>	2019-01-10
<b>Kraj izdaje:</b>	Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
<b>Datum izdaje:</b>	2025-06-10
<b>Revizija:</b>	36



## Izjava O Skladnosti



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Izjavljamo, da je za izdajo te izjave o skladnosti odgovoren izključno proizvajalec in da zgoraj navedeni izdelek(-ki) izpolnjuje(-jo) določbe UREDBE (EU) 2017/745 o medicinskih pripomočkih, spremembi Direktive 2001/83/ES, Uredbe (ES) št. 178/2002 in Uredbe (ES) št. 1223/2009 ter razveljavitvi direktiv Sveta 90/385/EGS in 93/42/EGS. Izdelek je bil predmet postopkov ugotavljanja skladnosti v skladu z Uredbo EU o medicinskih pripomočkih. Vsa pripadajoča dokumentacija je shranjena v prostorih proizvajalca.

Podpisano za in v imenu Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK – glejte podpisno stran spodaj.

**Izdelek** **0724995LCPITSTCNTRLINTE**  
**&** 2302 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
**Osnovni** 2317 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
**UDI-DI:** 2340 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2341 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2342 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2375 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
3103 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3104 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins Self-adhesive  
3105 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins Self-adhesive  
3107 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins Self-adhesive  
3108 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins Self-adhesive  
3702 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 9 mins  
3706 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins  
3725 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 mins  
Self Adhesive  
3726 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
Self Adhesive  
3727 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3760 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 min  
5006 - Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins  
5017 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins

**0724995LCPISTEAMINDZK**

2551 - Multi Variable MVI Steam Sterilization Indicator

**0724995LCPIFORMHYDINDBK**

2402 - Process Formaldehyde Indicator Spots

**0724995LCPIBROWNESMIND9**

3100 - Browne Steam Integrating Indicator Type 5

3101 - Browne Steam Integrating Indicator Type 5

3789-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm

**0724995LCPIVHPINDEC**

2501 - Multi Variable VAPOUR STRIP Multi-Variable Indicator for Vaporised Hydrogen Peroxide

**0724995LCPIGAMMARADINQT**

3301 - Process Gamma Check Indicator Spots

**0724995LCPIFORMHYDINDBK**

2401 - Multi-Variable Formaldehyde Multi-Variable Control Indicator

<b>Tillverkarens namn och adress:</b>	Albert Browne Ltd Chancery House Rayns Way Watermead Business Park Syston Leicester LE7 1PF UK
<b>Tillverkarens enskilda registreringsnummer (SRN)</b>	GB-MF-000017372
<b>Namn och adress till auktoriserad representant:</b>	STERIS Ireland Ltd IDA Business and Technology Park Tullamore County Offaly R35 X865 Ireland
<b>Auktoriserad representants SRN:</b>	IE-AR-000010065
<b>Grundläggande UDI-DI:</b>	Se nästa sida i denna deklARATION för grundläggande UDI-DI-detalljer.
<b>Produkt:</b>	Processindikatorer Se nästa sida i denna deklARATION för produktdetalljer.
<b>Avsett ändamål:</b>	Processindikatorerna är utformade för att visa om en last har bearbetats genom en steriliseringsprocess med en färgförändring eller annan fysisk förändring. Dessa indikatorer placeras vanligtvis antingen inuti brickan, förpackningen eller påsen, som ska steriliseras för att säkerställa att steriliseringsvillkoren har uppfyllts, eller på utsidan av brickan, förpackningen eller påsen så att bearbetade och obearbetade föremål snabbt kan identifieras. Processindikatorer kan också vara i form av självhäftande etiketter. Processindikatorsortimentet innehåller följande undersortiment: 1] Indikatorer för förångad väteperoxid 2] Ångindikatorer 3] Etylenoxidindikatorer 4] Formaldehydindikatorer 5] Indikatorer för flytande kemiskt steriliseringsmedel med perättiksyra 6] Gammastrålningsindikatorer 7] Indikatorer för torr värme
<b>Klassificering:</b>	Klass I icke-sterila, icke-mätande, ej återanvändbara enheter enligt regel 1 i bilaga VIII
<b>Använda gemensamma specifikationer:</b>	N/A
<b>ISO 13485 certifikatsnr:</b>	MD 504862
<b>Början av CE-märkning:</b>	2019-01-10
<b>Utfärdad på platsen:</b>	Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
<b>Utfärdandedatum:</b>	2025-06-10
<b>Revision:</b>	36



Vi förklarar härmed att denna försäkran om överensstämmelse utfärdas under tillverkarens ensamma ansvar och att ovannämnda produkter uppfyller bestämmelserna i FÖRORDNING (EU) 2017/745 för medicintekniska produkter (MDR) om ändring av direktiv 2001/83/EG, förordning (EG) nr 178/2002 och förordning (EG) nr 1223/2009 och om upphävande av rådets direktiv 90/385/EEG och 93/42/EEG. Produkten har utsatts för bedömningar av överensstämmelse enligt EU MDR. All underlagsdokumentation bevaras i tillverkarens lokaler.

Undertecknat för, och på uppdrag av Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK – Se signatursidan nedan.

**Produkt &  
Grundläggande  
UDI-DI:****0724995LCPITSTCNTRLINTE**

- 2302 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins
- 2317 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins
- 2340 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins
- 2341 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins
- 2342 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins
- 2375 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins
- 3103 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive
- 3104 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins Self-adhesive
- 3105 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins Self-adhesive
- 3107 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins Self-adhesive
- 3108 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins Self-adhesive
- 3702 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 9 mins
- 3706 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins
- 3725 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 mins Self Adhesive
- 3726 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins Self Adhesive
- 3727 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive
- 3760 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 min
- 5006 - Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins
- 5017 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins
- 121180 - Emulating TST Control™ Steam Cycle Verification Indicator 5.3 mins / 134 °C

**0724995LCPISTEAMINDZK**

- 2551 - Multi Variable MVI Steam Sterilization Indicator

**0724995LCCELERITYHPCIST**

- PCC075 - Celerity™ HP Chemical Indicator / Indicador Quimico HP
- PCC079 - Celerity™ HP Multivariable Chemical Indicator / Indicador Quimico Multivariable HP

**0724995LCPIBROWNESMIND9**

- 3100 - Browne Steam Integrating Indicator Type 5
- 3101 - Browne Steam Integrating Indicator Type 5
- 3789-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm

**0724995LCPIVHPINDEC**

- 2501 - Multi Variable VAPOUR STRIP Multi-Variable Indicator for Vaporised Hydrogen Peroxide

**0724995LCPICNTRLTUBE6K**

- 7301 - Sterilizer Control Tubes Type 1 (Black Spot) 121 °C / 15 min
- 7302 - Sterilizer Control Tubes Type 2 (Yellow Spot) 134 °C / 3 min
- 7303 - Sterilizer Control Tubes Type 3 (Green Spot) 160 °C / 60 min
- 7304 - Sterilizer Control Tubes Type 4 (Blue Spot) 180 °C / 12 min
- 7305 - Sterilizer Control Tubes Type 5 (White Spot) 160 °C / 120 min, 170 °C / 65 min, 180 °C / 35 min

**0724995LCPIGAMMARADINQT**

- 3301 - Process Gamma Check Indicator Spots

**0724995LCPIFORMHYDINDBK**

- 2401 - Multi-Variable Formaldehyde Multi-Variable Control Indicator



## UYGUNLUK BEYANI



tr

**Üreticinin Adı ve Adresi:** Albert Browne Ltd  
Chancery House  
Rayns Way  
Watermead Business Park  
Syston  
Leicester  
LE7 1PF  
UK

**Üretici Münferit Kayıt Numarası (SRN)** GB-MF-000017372

**Yetkili Temsilcinin Adı ve Adresi:** STERIS Ireland Ltd  
IDA Business and Technology Park  
Tullamore  
County Offaly  
R35 X865  
Ireland

**Yetkili Temsilci SRN'si:** IE-AR-000010065

**Temel UDI-DI:** Temel UDI-DI ayrıntıları için bu beyanın sonraki sayfasına bakın.

**Ürün:** Proses Göstergeleri Serisi  
Ürün ayrıntıları için bu beyanın sonraki sayfasına bakın.

**Kullanım Amacı:** Proses Göstergeleri Serisi, bir yükün renk değişimi veya başka bir fiziksel değişim yoluyla bir sterilizasyon prosesi yoluyla işlenip işlenmediğini göstermek üzere tasarlanmıştır. Bu göstergeler tipik olarak sterilizasyon koşullarının karşılandığından emin olmak için sterilize edilecek tepsinin, paketin ya da kesenin içine ya da işlenmiş ve işlenmemiş öğelerin bir bakışta tespit edilebilmesi için tepsinin, paketin ya da kesenin dışına yerleştirilir. Proses göstergeleri ayrıca kendinden yapışkanlı etiketler şeklinde de olabilir. Proses Göstergeleri Serisi aşağıdaki alt aralıkları içerir:  
1] Buharlaştırılmış Hidrojen Peroksit göstergeleri  
2] Buhar göstergeleri  
3] Etilen Oksit göstergeleri  
4] Formaldehit göstergeleri  
5] Perasetik Asit sıvı kimyasal sterilize edici göstergeleri  
6] Gama Radyasyonu göstergeleri  
7] Kuru Isı göstergeleri

**Sınıflandırma:** Class I non-sterile, non-measuring, non-reusable devices according to Rule 1 of Annex VIII

**Kullanılan Ortak Özellikler:** N/A

**ISO 13485 Belgesi/Belgeleri No.:** MD 504862

**CE İşaretinin Başlangıcı:** 2019-01-10

**Verildiği Yer:** Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.

**Verildiği Tarih:** 2025-06-10

**Revizyon:** 36



Bu uygunluk beyanının yalnızca Üreticinin sorumluluğu altında yayınlandığını ve yukarıda belirtilen ürünün/ürünlerin, 2001/83/EC sayılı Direktifi, (EC) 178/2002 sayılı Yönetmeliği ve (EC) 1223/2009 sayılı Yönetmeliği değiştiren ve 90/385/EEC ve 93/42/EEC sayılı Konsey Direktiflerini yürürlükten kaldıran (AB) 2017/745 sayılı Tıbbi Cihazlar YÖNETMELİĞİ (MDR) hükümlerini karşıladığını beyan ederiz. Ürün, AB MDR'ye göre uygunluk değerlendirme prosedürlerine tabi tutulmuştur. Yukarıda belirtilen ürünün/ürünlerin, Avrupa Parlamentosu ve konseyin 08/06/2011 tarihli, elektrikli ve elektronik ekipmanda belirli tehlikeli maddelerin kullanımının kısıtlanmasına ilişkin 2011/65/EU (tadil edilmiş şekliyle) sayılı Tehlikeli Maddelerin Kısıtlanması (RoHS) direktifine uygun olduğunu beyan ederiz. Tüm destekleyici belgeler üreticinin tesislerinde saklanır.

Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK için ve adına imzalanmıştır – Aşağıdaki imza sayfasına bakın.

**Product & Basic** **0724995LCPIETHYOXIND95**  
2563 - BX250 Multi Variable Ethylene Oxide Sterilization Indicator

**UDI-DI:** **0724995LCPIFORMHYDINDBK**  
2401 - Multi-Variable Formaldehyde Multi-Variable Control Indicator

**0724995LCPISTEAMINDZK**  
2551 - Multi Variable MVI Steam Sterilization Indicator

**0724995LCPITSTCNTRLINTE**  
2302 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2317 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2340 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2341 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2342 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2375 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
3103 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3104 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins Self-adhesive  
3105 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins Self-adhesive  
3107 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins Self-adhesive  
3108 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins Self-adhesive  
3702 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 9 mins  
3706 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins  
3725 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 mins Self Adhesive  
3726 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins Self Adhesive  
3727 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3760 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 min  
5006 - Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins  
5006-800 - Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins  
5017 - Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins

**0724995LCPIBROWNESMIND9**  
3100 - Browne Steam Integrating Indicator Type 5  
3101 - Browne Steam Integrating Indicator Type 5  
3789-24 - Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm

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PCC075 - Celerity™ HP Chemical Indicator / Indicador Quimico HP  
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