



Declaration of Conformity



en

Class I non-sterile, non-measuring devices

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

**Single Registration
Number (SRN):** -

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

Product: **Steam Penetration Test Range**
See the next page of this declaration for product details.

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

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

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

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

Start of CE Marking: 2019-01-24

Place, Date of Issue: Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
2021-10-14

Quality Approval

Signature:

Date: 5 1 10 21

Name and Title: S. Hammond, Quality Director

Regulatory Approval

Signature:

Date: 13 Oct 2021

Name and Title: L. Ballard, Regulatory & Quality Compliance Director



Declaration of Conformity



en

Product and Basic UDI-DI: **Bowie Dick Test Pack - 0724995LCPENBOWIEDICK23**
2310 Specific TST Bowie Dick Test Pack 121°C-124°C / 8 - 8.3 minutes
2352 Specific TST Bowie Dick Test Pack 134°C-137°C / 3.5 minutes
2356 Specific TST Bowie Dick Test Pack Single Use W&H 134°C-137°C / 3.5 minutes
2358 Specific TST Bowie Dick Test Pack Eschmann 134°C-137°C / 3 - 3.5 minutes
2368 Specific TST Single Use Bowie Dick Type Test Pack Euronda Autoclaves 134°C / 3.5 minutes
2385 Specific Sensor Chemical Indicator Test Sheet
6536 Specific TST Bowie Dick Test Pack Getinge 134°C-137°C / 3 - 3.5 minutes

Helix Load Test - 0724995LCPENHELIXLOAD37

3780 Specific TST Helix
3781 Specific TST Helix Starter Pack
2367 Euronda TST Helix Daily Steam Penetration Test 132°C - 137°C

Ball Type - 0724995LCPENBALLTYPER2

AB101 Porous & Hollow Steam Penetration Test 134°C-137°C / 3.5 minutes

Helix Load Test-NSK - 0724995LCNSKHELIXTESTEL

9900059 Helix Test for Steam Sterilizers

Top Dent Helix - 0724995LCTOPDENTHELIXGG

121184 Top Dent Helix Daily Steam Penetration Test 132°C - 137°C

W&H Helix - 0724995LCWHHELIXQ5

3784 TST Helix T800203X Daily Steam Penetration Test 132°C - 137°C
3804 TST Helix T800205X Daily Steam Penetration Test 132°C - 137°C
3805 TST Helix T801003X Daily Steam Penetration Test 132°C - 137°C

MELAG Load Test - 0724995LCMELCNTTESTLC55

ME01080 MELAcontrol Helix

Helix or Hollow Load Test Type - 0724995LCESCHMNESHLDVUH

8793436 essential Helix Load Test Device and TST Indicators 134°C / 3.5 minutes



ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ STERIS

bg

Клас I нестерилни, неизмервателни изделия

Производител: Albert Browne Ltd
Chancery House
Rayns Way
Watermead Business Park
Syston
Leicester
LE7 1PF
UK

Единен регистрационен номер (EPN) -

Упълномощен представител: STERIS Ireland Ltd
IDA Business and Technology Park
Tullamore
County Offaly
R35 X865
Ireland

Изделие: **Steam Penetration Test Range**
See the next page of this declaration for product details.

Основен UDI-DI (уникален идентификатор на изделие-идентификатор на изделие): See the next page of this declaration for Basic UDI-DI details.

Класификация: Клас I нестерилни, неизмервателни изделия съгласно правило ____ от Приложение VIII

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/ЕО и 93/42/ЕО на Съвета. Изделието е било подложено на процедури за оценка на съответствието съгласно РМД на ЕС. Всички допълнителни документи се съхраняват от производителя.

Сертификат(и) ISO Certificate Number MD 504862
13485 №

Начало на маркировка CE: 2019-01-24

Място, дата на издаване: Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
2021-10-14

Техническо одобрение

Подпис: 

Дата: 5 ' 10 ' 21

Име и длъжност: S. Hammond, Quality Director

Регулаторно одобрение

Подпис: 

Дата: 13 Oct 2021
/ /

Име и длъжност: L. Ballard, Regulatory & Quality Compliance Director



Изделие & Основен UDI-DI (уникален идентификатор на изделие-идентификатор на изделие):	Bowie Dick Test Pack - 0724995LCPENBOWIEDICK23 2352 Specific TST Bowie Dick Test Pack 134°C-137°C / 3.5 minutes
	Helix Load Test - 0724995LCPENHELIXLOAD37 2367 Euronda TST Helix Daily Steam Penetration Test 132°C - 137°C



PROHLÁŠENÍ O SHODĚ



CS

Třída I nesterilní, neměřicí zařízení

Výrobce: Albert Browne Ltd
Chancery House
Rayns Way
Watermead Business Park
Syston
Leicester
LE7 1PF
UK

**Jedinečné
registrační číslo
(SRN)**

-

**Oprávněný
zástupce:** STERIS Ireland Ltd
IDA Business and Technology Park
Tullamore
County Offaly
R35 X865
Ireland

Výrobek: **Steam Penetration Test Range**
See the next page of this declaration for product details.

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

Klasifikace: Třída I nesterilní, neměřicí zařízení, podle Pravidla 1 Přílohy VIII

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 směrnice 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.

**Č. certifikátu/-ů ISO
13485:** Certificate Number MD 504862

**Zahájení získání
označení CE:** 2019-01-24

**Místo, datum
vystavení:** Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business
Park, Syston, Leicester, LE7 1PF, UK.
2021-10-14

Technické schválení

Podpis: 

Datum: 5. 10. 21

Jméno a titul: S. Hammond, Quality Director

Regulatorní souhlas

Podpis: 

Datum: 13 Oct 2021

Jméno a titul: L. Ballard, Regulatory & Quality Compliance Director



Výrobek & Bowie Dick Test Pack - 0724995LCPENBOWIEDICK23
Základní UDI- 2352 Specific TST Bowie Dick Test Pack 134°C-137°C / 3.5 minutes
DI: 2356 Specific TST Bowie Dick Test Pack Single Use W&H 134°C-137°C / 3.5 minutes

Helix Load Test - 0724995LCPENHELIXLOAD37
3780 Specific TST Helix
3781 Specific TST Helix Starter Pack
2367 Euronda TST Helix Daily Steam Penetration Test 132°C - 137°C

Top Dent Helix - 0724995LCTOPDENTHELIXGG
121184 Top Dent Helix Daily Steam Penetration Test 132°C - 137°C

W&H Helix - 0724995LCWHHELIXQ5
3804 TST Helix T800205X Daily Steam Penetration Test 132°C - 137°C
3805 TST Helix T801003X Daily Steam Penetration Test 132°C - 137°C

MELAG Load Test - 0724995LCMELCNTTESTLC55
ME01080 MELAcontrol Helix

Ball Type - 0724995LCPENBALLTYPER2
AB101 Porous & Hollow Steam Penetration Test 134°C-137°C / 3.5 minutes



Klasse I ikke-sterile, ikke-målende enheder

Producent: Albert Browne Ltd
Chancery House
Rayns Way
Watermead Business Park
Syston
Leicester
LE7 1PF
UK

**Enkelt
registreringsnummer
(SRN):** -

**Autoriseret
repræsentant:** STERIS Ireland Ltd
IDA Business and Technology Park
Tullamore
County Offaly
R35 X865
Ireland

Produkt: **Steam Penetration Test Range**
See the next page of this declaration for product details.

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

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

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.

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

Start på CE-mærkning: 2019-01-24

Sted, udstedelsesdato: Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
2021-10-14

Teknisk godkendelse

Underskrift:

Dato: 5 / 10 / 21

Navn og titel: S. Hammond, Quality Director

Lovmæssig godkendelse

Underskrift:

Dato: 13 Oct 2021

Navn og titel: L. Ballard, Regulatory & Quality Compliance Director



Produkt & Basal UDI- **Bowie Dick Test Pack - 0724995LCPENBOWIEDICK23**
DI: 2310 Specific TST Bowie Dick Test Pack 121°C-124°C / 8 - 8.3 minutes
2352 Specific TST Bowie Dick Test Pack 134°C-137°C / 3.5 minutes

Helix Load Test - 0724995LCPENHELIXLOAD37
3780 Specific TST Helix
3781 Specific TST Helix Starter Pack
2367 Euronda TST Helix Daily Steam Penetration Test 132°C - 137°C

Ball Type - 0724995LCPENBALLTYPER2
AB101 Porous & Hollow Steam Penetration Test 134°C-137°C / 3.5 minutes

Helix Load Test-NSK - 0724995LCNSKHELIXTESTEL
9900059 Helix Test for Steam Sterilizers

Top Dent Helix - 0724995LCTOPDENTHELIXGG
121184 Top Dent Helix Daily Steam Penetration Test 132°C - 137°C

W&H Helix - 0724995LCWHHELIXQ5
3804 TST Helix T800205X Daily Steam Penetration Test 132°C - 137°C
3805 TST Helix T801003X Daily Steam Penetration Test 132°C - 137°C

MELAG Load Test - 0724995LCMELCNTTESTLC55
ME01080 MELAcontrol Helix



Nicht sterile Vorrichtungen der Klasse I ohne Messfunktion

Hersteller: Albert Browne Ltd
Chancery House
Rayns Way
Watermead Business Park
Syston
Leicester
LE7 1PF
UK

Einmalige -
Registrierungsnummer

(SRN):

Autorisierter Vertreter: STERIS Ireland Ltd
IDA Business and Technology Park
Tullamore
County Offaly
R35 X865
Ireland

Produkt: **Steam Penetration Test Range**
See the next page of this declaration for product details.

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

Klassifizierung: Klasse I nicht sterile Vorrichtungen ohne Messfunktion, gemäß Regel 1 von Anhang VIII

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.

ISO-13485-Zertifikat(e) Certificate Number MD 504862
Nr.:

Beginn der CE- 2019-01-24
Kennzeichnung:

Ort, Datum der Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business
Ausstellung: Park, Syston, Leicester, LE7 1PF, UK.
2021-10-14

Technische Zulassung

Unterschrift:

Datum:

5, 10, 21

Name und Titel: S. Hammond, Quality Director

Marktzulassung

Unterschrift:

13 Oct 2021

Datum:

/ /

Name und Titel: L. Ballard, Regulatory & Quality Compliance Director



Produkt & Basis-UDI-DI: **Bowie Dick Test Pack - 0724995LCPENBOWIEDICK23**
2310 Specific TST Bowie Dick Test Pack 121°C-124°C / 8 - 8.3 minutes
2352 Specific TST Bowie Dick Test Pack 134°C-137°C / 3.5 minutes
2356 Specific TST Bowie Dick Test Pack Single Use W&H 134°C-137°C / 3.5 minutes
6536 Specific TST Bowie Dick Test Pack Getinge 134°C-137°C / 3 - 3.5 minutes

Helix Load Test - 0724995LCPENHELIXLOAD37
3780 Specific TST Helix
3781 Specific TST Helix Starter Pack
2367 Euronda TST Helix Daily Steam Penetration Test 132°C - 137°C

Ball Type - 0724995LCPENBALLTYPER2
AB101 Porous & Hollow Steam Penetration Test 134°C-137°C / 3.5 minutes

Helix Load Test-NSK - 0724995LCNSKHELIXTESTEL
9900059 Helix Test for Steam Sterilizers

Top Dent Helix - 0724995LCTOPDENTHELIXGG
121184 Top Dent Helix Daily Steam Penetration Test 132°C - 137°C

W&H Helix - 0724995LCWHHELIXQ5
3804 TST Helix T800205X Daily Steam Penetration Test 132°C - 137°C
3805 TST Helix T801003X Daily Steam Penetration Test 132°C - 137°C

MELAG Load Test - 0724995LCMELCNTTESTLC55
ME01080 MELAcontrol Helix



Κλάση I μη αποστειρωμένες, χωρίς οργανολογία μέτρησης συσκευές

Κατασκευαστής: Albert Browne Ltd
Chancery House
Rayns Way
Watermead Business Park
Syston
Leicester
LE7 1PF
UK

Ενιαίος Αριθμός -
Καταχώρισης (SRN):
Εξουσιοδοτημένος
αντιπρόσωπος: STERIS Ireland Ltd
IDA Business and Technology Park
Tullamore
County Offaly
R35 X865
Ireland

Προϊόν: **Steam Penetration Test Range**
See the next page of this declaration for product details.

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

Ταξινόμηση: Κλάση I μη αποστειρωμένες, χωρίς οργανολογία μέτρησης συσκευές
σύμφωνα με τον Κανόνα 1 του Παραρτήματος VIII

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

Πιστοποιητικό(-ά) Certificate Number MD 504862
ISO 13485 #:

Έναρξη σήμανσης 2019-01-24
CE:

Τόπος, Ημερομηνία Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business
έκδοσης: Park, Syston, Leicester, LE7 1PF, UK.
2021-10-14

Τεχνική έγκριση

Υπογραφή:

Ημερομηνία: 5 / 10 / 21

Ονομασία και
Τίτλος: S. Hammond, Quality Director

Κανονιστική έγκριση

Υπογραφή:

Ημερομηνία: 13 Oct 2021
/ /

Ονομασία και
Τίτλος: L. Ballard, Regulatory & Quality Compliance Director



Προϊόν & Βασικός UDI-DI: **Bowie Dick Test Pack - 0724995LCPENBOWIEDICK23**
2310 Specific TST Bowie Dick Test Pack 121°C-124°C / 8 - 8.3 minutes

Helix Load Test - 0724995LCPENHELIXLOAD37
2367 Euronda TST Helix Daily Steam Penetration Test 132°C - 137°C



Clase I no estéril, dispositivos sin función de medición

Fabricante: Albert Browne Ltd
Chancery House
Rayns Way
Watermead Business Park
Syston
Leicester
LE7 1PF
UK

**Número de registro
único (NRU):** -

**Representante
autorizado:** STERIS Ireland Ltd
IDA Business and Technology Park
Tullamore
County Offaly
R35 X865
Ireland

Producto: **Steam Penetration Test Range**
See the next page of this declaration for product details.

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

Clasificación: Clase I no estéril, dispositivos sin función de medición, según la regla 1 del anexo VIII

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.

N.º de certificado(s) Certificate Number MD 504862
ISO 13485:

**Inicio de la marca
CE:** 2019-01-24

**Lugar y fecha de
publicación:** Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business
Park, Syston, Leicester, LE7 1PF, UK.
2021-10-14

Aprobación técnica

Firma:

Fecha: 5 / 10 / 21

Nombre y cargo: S. Hammond, Quality Director

Aprobación reglamentaria

Firma:

Fecha: 13 Oct 2021
/ /

Nombre y cargo: L. Ballard, Regulatory & Quality Compliance Director



Producto & UDI-DI básico: **Bowie Dick Test Pack - 0724995LCPENBOWIEDICK23**
2310 Specific TST Bowie Dick Test Pack 121°C-124°C / 8 - 8.3 minutes
2352 Specific TST Bowie Dick Test Pack 134°C-137°C / 3.5 minutes
2356 Specific TST Bowie Dick Test Pack Single Use W&H 134°C-137°C / 3.5 minutes
6536 Specific TST Bowie Dick Test Pack Getinge 134°C-137°C / 3 - 3.5 minutes

Helix Load Test - 0724995LCPENHELIXLOAD37

3780 Specific TST Helix
3781 Specific TST Helix Starter Pack
2367 Euronda TST Helix Daily Steam Penetration Test 132°C - 137°C

Ball Type - 0724995LCPENBALLTYPER2

AB101 Porous & Hollow Steam Penetration Test 134°C-137°C / 3.5 minutes

Helix Load Test-NSK - 0724995LCNSKHELIXTESTEL

9900059 Helix Test for Steam Sterilizers

Top Dent Helix - 0724995LCTOPDENTHELIXGG

121184 Top Dent Helix Daily Steam Penetration Test 132°C - 137°C

W&H Helix - 0724995LCWHHELIXQ5

3804 TST Helix T800205X Daily Steam Penetration Test 132°C - 137°C
3805 TST Helix T801003X Daily Steam Penetration Test 132°C - 137°C

I klassi mittesteriilsed mõõtefunktsioonita seadmed

Tootja: Albert Browne Ltd
Chancery House
Rayns Way
Watermead Business Park
Syston
Leicester
LE7 1PF
UK

**Unikaalne
registreerimisnumber**

-

Volitatud esindaja: STERIS Ireland Ltd
IDA Business and Technology Park
Tullamore
County Offaly
R35 X865
Ireland

Toode: **Steam Penetration Test Range**
See the next page of this declaration for product details.

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

Liigitus: Klass I mittesteriilsed mõõtefunktsioonita seadmed VIII lisa reegli 1 põhjal

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.

ISO 13485 Certificate Number MD 504862
sertifikaadi
(sertifikaatide) nr:
CE-märgistuse algus: 2019-01-24

Väljastamise koht ja Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business
kuupäev: Park, Syston, Leicester, LE7 1PF, UK.
2021-10-14

Tehniline heakskiit

Allkiri:



Kuupäev:

5.10.21

Nimi ja
ametnimetus: S. Hammond, Quality Director

Regulatoorne heakskiit

Allkiri:



Kuupäev:

13 Oct 2021

Nimi ja
ametnimetus: L. Ballard, Regulatory & Quality Compliance Director



Toode & Põhi-UDI-DI: **Bowie Dick Test Pack - 0724995LCPENBOWIEDICK23**
2352 Specific TST Bowie Dick Test Pack 134°C-137°C / 3.5 minutes

Helix Load Test - 0724995LCPENHELIXLOAD37
2367 Euronda TST Helix Daily Steam Penetration Test 132°C - 137°C

Top Dent Helix - 0724995LCTOPDENTHELIXGG
121184 Top Dent Helix Daily Steam Penetration Test 132°C - 137°C



Luokan I epästeriilit, ei mittaavat laitteet

Valmistaja: Albert Browne Ltd
Chancery House
Rayns Way
Watermead Business Park
Syston
Leicester
LE7 1PF
UK

Yksilöllinen rekisteröintitunnus (SRN): -
Valtuutettu edustaja: STERIS Ireland Ltd
IDA Business and Technology Park
Tullamore
County Offaly
R35 X865
Ireland

Tuote: **Steam Penetration Test Range**
See the next page of this declaration for product details.

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

Luokitus: Luokan I epästeriilit, ei mittaavat laitteet liitteen VIII säännön 1 mukaan

Ilmoitamme täten, että tämä vaatimustenmukaisuusvakuutus on julkaistu valmistajan yksinomaisella vastuulla ja yllä mainitut tuotteet noudattavat Euroopan parlamentin ja neuvoston ASETUSTA (EU) 2017/745 lääkinnällisistä 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.

ISO 13485 -sertifikaattien numerot: Certificate Number MD 504862
CE-merkinnän alkamispäivämäärä: 2019-01-24

Paikka, antamispäivämäärä: Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
2021-10-14

Tekninen hyväksyntä

Allekirjoitus:  **Päivämäärä:** 5 / 10 / 21
Nimi ja titteli: S. Hammond, Quality Director

Säätelyn mukainen hyväksyntä

Allekirjoitus:  **Päivämäärä:** 13 Oct 2021
Nimi ja titteli: L. Ballard, Regulatory & Quality Compliance Director



Tuote & Perustasoinen UDI-DI: **Bowie Dick Test Pack - 0724995LCPENBOWIEDICK23**
2310 Specific TST Bowie Dick Test Pack 121°C-124°C / 8 - 8.3 minutes
2352 Specific TST Bowie Dick Test Pack 134°C-137°C / 3.5 minutes

Helix Load Test - 0724995LCPENHELIXLOAD37
3780 Specific TST Helix
3781 Specific TST Helix Starter Pack
2367 Euronda TST Helix Daily Steam Penetration Test 132°C - 137°C

Ball Type - 0724995LCPENBALLTYPER2
AB101 Porous & Hollow Steam Penetration Test 134°C-137°C / 3.5 minutes

Helix Load Test-NSK - 0724995LCNSKHELIXTESTEL
9900059 Helix Test for Steam Sterilizers

Top Dent Helix - 0724995LCTOPDENTHELIXGG
121184 Top Dent Helix Daily Steam Penetration Test 132°C - 137°C

W&H Helix - 0724995LCWHHELIXQ5
3804 TST Helix T800205X Daily Steam Penetration Test 132°C - 137°C
3805 TST Helix T801003X Daily Steam Penetration Test 132°C - 137°C

MELAG Load Test - 0724995LCMELCNTTESTLC55
ME01080 MELAcontrol Helix



Classe I non stérile, dispositifs sans fonction de mesure

Fabricant: Albert Browne Ltd
Chancery House
Rayns Way
Watermead Business Park
Syston
Leicester
LE7 1PF
UK

**Numéro
d'enregistrement
unique (NEU):** -

**Représentant
autorisé:** STERIS Ireland Ltd
IDA Business and Technology Park
Tullamore
County Offaly
R35 X865
Ireland

Produit: **Steam Penetration Test Range**
See the next page of this declaration for product details.

IUD-ID de base: See the next page of this declaration for Basic UDI-DI details.

Classification: Classe I non stérile, dispositifs sans fonction de mesure, conformément à la règle 1 de l'annexe VIII

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

**ISO 13485 Numéro
de certificat(s) :** Certificate Number MD 504862

**Début du marquage
CE:** 2019-01-24

**Lieu, date de
délivrance:** Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business
Park, Syston, Leicester, LE7 1PF, UK.
2021-10-14

Approbation technique

Signature:

Date:

5 / 10 / 21

Nom et titre: S. Hammond, Quality Director

Approbation réglementaire

Signature:

Date:

13 Oct 2021
/ /

Nom et titre: L. Ballard, Regulatory & Quality Compliance Director



Déclaration de Conformité



fr

**Produit &
IUD-ID de
base:**

Bowie Dick Test Pack - 0724995LCPENBOWIEDICK23

2310 Specific TST Bowie Dick Test Pack 121°C-124°C / 8 - 8.3 minutes

2352 Specific TST Bowie Dick Test Pack 134°C-137°C / 3.5 minutes

2356 Specific TST Bowie Dick Test Pack Single Use W&H 134°C-137°C / 3.5 minutes

6536 Specific TST Bowie Dick Test Pack Getinge 134°C-137°C / 3 - 3.5 minutes

Helix Load Test - 0724995LCPENHELIXLOAD37

3780 Specific TST Helix

3781 Specific TST Helix Starter Pack

2367 Euronda TST Helix Daily Steam Penetration Test 132°C - 137°C

Ball Type - 0724995LCPENBALLTYPER2

AB101 Porous & Hollow Steam Penetration Test 134°C-137°C / 3.5 minutes

Helix Load Test-NSK - 0724995LCNSKHELIXTESTEL

9900059 Helix Test for Steam Sterilizers

Top Dent Helix - 0724995LCTOPDENTHELIXGG

121184 Top Dent Helix Daily Steam Penetration Test 132°C - 137°C

W&H Helix - 0724995LCWHHELIXQ5

3804 TST Helix T800205X Daily Steam Penetration Test 132°C - 137°C

3805 TST Helix T801003X Daily Steam Penetration Test 132°C - 137°C

MELAG Load Test - 0724995LCMELCNTTESTLC55

ME01080 MELAcontrol Helix

Nesterilni proizvodi bez mjerne funkcije I. klase

Proizvođač: Albert Browne Ltd
Chancery House
Rayns Way
Watermead Business Park
Syston
Leicester
LE7 1PF
UK

**Jedinstveni
registracijski broj
(SRN)** -

Ovlašteni zastupnik: STERIS Ireland Ltd
IDA Business and Technology Park
Tullamore
County Offaly
R35 X865
Ireland

Proizvod: **Steam Penetration Test Range**
See the next page of this declaration for product details.

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

Razvrstavanje: Klasa nesterilni proizvodi bez mjerne funkcije I. klase u skladu s pravilom 1 iz Priloga VIII

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.

Br. ISO 13485 Certificate Number MD 504862
certifikata:

**Početak označavanja
oznakom CE:** 2019-01-24

**Mjesto i datum
izdavanja:** Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business
Park, Syston, Leicester, LE7 1PF, UK.
2021-10-14

Tehničko odobrenje

Potpis: 

Datum: 5. 10. 21

Ime i titula: S. Hammond, Quality Director

Odobrenje odjela za regulatorna pitanja

13 Oct 2021

Potpis: 

Datum: / /

Ime i titula: L. Ballard, Regulatory & Quality Compliance Director

Predložak izjave o sukladnosti (Uredba o medicinskim proizvodima EU-a) SCS-148-TM-005 nesterilni proizvodi bez mjerne funkcije I. klase Inačica 2



IZJAVA O SUKLADNOSTI



hr

Proizvod & Bowie Dick Test Pack - 0724995LCPENBOWIEDICK23
Osnovni UDI-DI: 2352 Specific TST Bowie Dick Test Pack 134°C-137°C / 3.5 minutes

Helix Load Test - 0724995LCPENHELIXLOAD37
2367 Euronda TST Helix Daily Steam Penetration Test 132°C - 137°C

I. osztályú nem steril, nem mérő eszközök

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

**Egyedi regisztrációs
szám (SRN)** -

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

Termék: **Steam Penetration Test Range**
See the next page of this declaration for product details.

**Alapvető egyedi
eszközzazonosító
(UDI-DI):** See the next page of this declaration for Basic UDI-DI details.

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

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 orvostechnikai 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.

ISO 13485 Certificate Number MD 504862

Tanúsítvány(ok) #:

CE jelölés kezdete: 2019-01-24

**Kiadás
helye/időpontja:** Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business
Park, Syston, Leicester, LE7 1PF, UK.
2021-10-14

Műszaki Engedély

Aláírás:

Dátum:

5.10.21

Név és cím: S. Hammond, Quality Director

Hatósági engedély

Aláírás:

13 Oct 2021

Dátum:

/ /

Név és cím: L. Ballard, Regulatory & Quality Compliance Director



**Termék &
Alapvető egyedi
eszközzazonosító
(UDI-DI):**

Bowie Dick Test Pack - 0724995LCPENBOWIEDICK23

2310 Specific TST Bowie Dick Test Pack 121°C-124°C / 8 - 8.3 minutes
2352 Specific TST Bowie Dick Test Pack 134°C-137°C / 3.5 minutes
2385 Specific Sensor Chemical Indicator Test Sheet

Helix Load Test - 0724995LCPENHELIXLOAD37

3780 Specific TST Helix
3781 Specific TST Helix Starter Pack
2367 Euronda TST Helix Daily Steam Penetration Test 132°C - 137°C

Ball Type - 0724995LCPENBALLTYPER2

AB101 Porous & Hollow Steam Penetration Test 134°C-137°C / 3.5 minutes

Helix Load Test-NSK - 0724995LCNSKHELIXTESTEL

9900059 Helix Test for Steam Sterilizers

Top Dent Helix - 0724995LCTOPDENTHELIXGG

121184 Top Dent Helix Daily Steam Penetration Test 132°C - 137°C

W&H Helix - 0724995LCWHHELIXQ5

3804 TST Helix T800205X Daily Steam Penetration Test 132°C - 137°C
3805 TST Helix T801003X Daily Steam Penetration Test 132°C - 137°C



Dispositivi di Classe I non sterili, non di misura

Fabbricante: Albert Browne Ltd
Chancery House
Rayns Way
Watermead Business Park
Syston
Leicester
LE7 1PF
UK

Numero unico di registrazione (SRN): -

Rappresentante autorizzato: STERIS Ireland Ltd
IDA Business and Technology Park
Tullamore
County Offaly
R35 X865
Ireland

Prodotto: **Steam Penetration Test Range**
See the next page of this declaration for product details.

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

Classificazione: Dispositivi di Classe I non sterili, non di misura ai sensi della norma 1 dell'Allegato VIII

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.

Certificazione ISO 13485 n.: Certificate Number MD 504862

Inizio della marcatura CE: 2019-01-24

Luogo e data di rilascio: Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
2021-10-14

Approvazione tecnica

Firma:

Data: 5 / 10 / 21

Nome e qualifica: S. Hammond, Quality Director

Approvazione regolatoria

Firma:

13 Oct 2021

Data: / /

Nome e qualifica: L. Ballard, Regulatory & Quality Compliance Director



Prodotto & UDI-DI di base: **Bowie Dick Test Pack - 0724995LCPENBOWIEDICK23**
2310 Specific TST Bowie Dick Test Pack 121°C-124°C / 8 - 8.3 minutes
2352 Specific TST Bowie Dick Test Pack 134°C-137°C / 3.5 minutes
2356 Specific TST Bowie Dick Test Pack Single Use W&H 134°C-137°C / 3.5 minutes
2368 Specific TST Single Use Bowie Dick Type Test Pack Euronda Autoclaves 134°C / 3.5 minutes
6536 Specific TST Bowie Dick Test Pack Getinge 134°C-137°C / 3 - 3.5 minutes

Helix Load Test - 0724995LCPENHELIXLOAD37
3780 Specific TST Helix
3781 Specific TST Helix Starter Pack
2367 Euronda TST Helix Daily Steam Penetration Test 132°C - 137°C

Ball Type - 0724995LCPENBALLTYPER2
AB101 Porous & Hollow Steam Penetration Test 134°C-137°C / 3.5 minutes

Helix Load Test-NSK - 0724995LCNSKHHELIXTESTEL
9900059 Helix Test for Steam Sterilizers

Top Dent Helix - 0724995LCTOPDENTHELIXGG
121184 Top Dent Helix Daily Steam Penetration Test 132°C - 137°C

W&H Helix - 0724995LCWHHELIXQ5
3804 TST Helix T800205X Daily Steam Penetration Test 132°C - 137°C
3805 TST Helix T801003X Daily Steam Penetration Test 132°C - 137°C

MELAG Load Test - 0724995LCMELCNTTESTLC55
ME01080 MELAcontrol Helix



ATITIKTIES DEKLARACIJA

STERIS

lt

I klasės nesterilios, neturinčios matavimo funkcijos priemonės

Gamintojas: Albert Browne Ltd
Chancery House
Rayns Way
Watermead Business Park
Syston
Leicester
LE7 1PF
UK

**Unikalasis registracijos
numeris (SRN):** -

Igaliotasis atstovas: STERIS Ireland Ltd
IDA Business and Technology Park
Tullamore
County Offaly
R35 X865
Ireland

Gaminys: **Steam Penetration Test Range**
See the next page of this declaration for product details.

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

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

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.

**ISO 13485 sertifikato (-ų)
Nr.:** Certificate Number MD 504862

**CE ženklavimo galiojimo
pradžia:** 2019-01-24

Išdavimo vieta ir data: Albert Browne Ltd, Chancery House, Rayns Way, Watermead
Business Park, Syston, Leicester, LE7 1PF, UK.
2021-10-14

Techninis liudijimas (patvirtinimas)

Parašas: *S. Hammond*

Data: 5, 10, 21.

**Vardas, pavardė ir
pareigos:** S. Hammond, Quality Director

Reguliavimo reikalų skyriaus liudijimas (patvirtinimas)

Parašas: *L. Ballard*

Data: 13 Oct 2021
/ /

**Vardas, pavardė ir
pareigos:** L. Ballard, Regulatory & Quality Compliance Director



Gaminys & Bazinis UDI-DI: **Bowie Dick Test Pack - 0724995LCPENBOWIEDICK23**
2352 Specific TST Bowie Dick Test Pack 134°C-137°C / 3.5 minutes

Helix Load Test - 0724995LCPENHELIXLOAD37
3780 Specific TST Helix
3781 Specific TST Helix Starter Pack
2367 Euronda TST Helix Daily Steam Penetration Test 132°C - 137°C

Top Dent Helix - 0724995LCTOPDENTHELIXGG
121184 Top Dent Helix Daily Steam Penetration Test 132°C - 137°C

W&H Helix - 0724995LCWHHELIXQ5
3804 TST Helix T800205X Daily Steam Penetration Test 132°C - 137°C
3805 TST Helix T801003X Daily Steam Penetration Test 132°C - 137°C

MELAG Load Test - 0724995LCMELCNTTESTLC55
ME01080 MELAcontrol Helix

Ball Type - 0724995LCPENBALLTYPER2
AB101 Porous & Hollow Steam Penetration Test 134°C-137°C / 3.5 minutes



I klases nesterilas, mērīšanai neparedzētas ierīces

Ražotājs: Albert Browne Ltd
Chancery House
Rayns Way
Watermead Business Park
Syston
Leicester
LE7 1PF
UK

Vienotais reģistrācijas numurs (Single Registration Number – SRN): -

Pilnvarotais pārstāvis: STERIS Ireland Ltd
IDA Business and Technology Park
Tullamore
County Offaly
R35 X865
Ireland

Izstrādājums: **Steam Penetration Test Range**
See the next page of this declaration for product details.

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

Klasifikācija: I klases nesterilas, mērīšanai neparedzētas ierīces saskaņā ar VIII pielikuma 1. Noteikumu

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 apliecinājošie dokumenti ir saglabāti ražotāja objektos.

ISO 13485 sertifikāta vai sertifikātu nr.: Certificate Number MD 504862

CE zīmes uzlikšanas datums: 2019-01-24

Izdošanas vieta un datums: Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
2021-10-14

Tehniskais apstiprinājums

Paraksts:

Datums:

5, 10, 21

Vārds, uzvārds un amata nosaukums:

S. Hammond, Quality Director

Apstiprinājums par atbilstību prasībām

Paraksts:

13 Oct 2021

Datums:

/ /

Vārds, uzvārds un amata nosaukums:

L. Ballard, Regulatory & Quality Compliance Director

SCS-148-TM-005 atbilstības deklarācijas veidne (saskaņā ar ES Medicīnisko ierīču regulu) I klases nesterila, mērīšanai neparedzēta ierīce 2. versija



Izstrādājums & Pamata UDI-DI: **Bowie Dick Test Pack - 0724995LCPENBOWIEDICK23**
2352 Specific TST Bowie Dick Test Pack 134°C-137°C / 3.5 minutes

Helix Load Test - 0724995LCPENHELIXLOAD37
2367 Euronda TST Helix Daily Steam Penetration Test 132°C - 137°C

Ball Type - 0724995LCPENBALLTYPER2
AB101 Porous & Hollow Steam Penetration Test 134°C-137°C / 3.5 minutes

Klasse I niet steriele, niet metende hulpmiddelen

Producent: Albert Browne Ltd
Chancery House
Rayns Way
Watermead Business Park
Syston
Leicester
LE7 1PF
UK

**Single Registration
Number (SRN):** -

**Bevoegde
vertegenwoordiger:** STERIS Ireland Ltd
IDA Business and Technology Park
Tullamore
County Offaly
R35 X865
Ireland

Product: **Steam Penetration Test Range**
See the next page of this declaration for product details.

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

Classificatie: Klasse I niet steriele, niet metende hulpmiddelen conform voorschrift 1
van Bijlage VIII

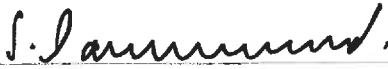
Hiermee verklaren we dat deze conformiteitsverklaring onder de uitsluitende verantwoordelijkheid van de Producent wordt verstrekt en dat bovengenoemd(e) product(en) voldoet(n) aan de bepalingen van EU-VERORDENING 2017/745 voor Medische hulpmiddelen (MDR) en houdende wijziging van Richtlijn 2001/83/EG, 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 bedrijfspan van de producent bewaard.

ISO 13485- Certificate Number MD 504862
certificaat/certificaten nr.:

Ingangsdatum CE- 2019-01-24
markering:

Plaats, datum van Albert Browne Ltd, Chancery House, Rayns Way, Watermead
uitgifte: Business Park, Syston, Leicester, LE7 1PF, UK.
2021-10-14

Technische goedkeuring

Handtekening: 
Naam en functie: S. Hammond, Quality Director

Datum: 5, 10, 21

Handtekening: 
Naam en functie: L. Ballard, Regulatory & Quality Compliance Director

Interne goedkeuring

13 Oct 2021

Datum: / /

Product & Basic UDI-DI: **Bowie Dick Test Pack - 0724995LCPENBOWIEDICK23**
2310 Specific TST Bowie Dick Test Pack 121°C-124°C / 8 - 8.3 minutes
2352 Specific TST Bowie Dick Test Pack 134°C-137°C / 3.5 minutes
2356 Specific TST Bowie Dick Test Pack Single Use W&H 134°C-137°C / 3.5 minutes
6536 Specific TST Bowie Dick Test Pack Getinge 134°C-137°C / 3 - 3.5 minutes

Helix Load Test - 0724995LCPENHELIXLOAD37
3780 Specific TST Helix
3781 Specific TST Helix Starter Pack
2367 Euronda TST Helix Daily Steam Penetration Test 132°C - 137°C

Ball Type - 0724995LCPENBALLTYPER2
AB101 Porous & Hollow Steam Penetration Test 134°C-137°C / 3.5 minutes

Helix Load Test-NSK - 0724995LCNSKHHELIXTESTEL
9900059 Helix Test for Steam Sterilizers

Top Dent Helix - 0724995LCTOPDENTHELIXGG
121184 Top Dent Helix Daily Steam Penetration Test 132°C - 137°C

W&H Helix - 0724995LCWHHELIXQ5
3804 TST Helix T800205X Daily Steam Penetration Test 132°C - 137°C
3805 TST Helix T801003X Daily Steam Penetration Test 132°C - 137°C

MELAG Load Test - 0724995LCMELCNTTESTLC55
ME01080 MELAcontrol Helix



Deklaracja Zgodności



pl

Wyroby Klasy I, niesterylne, bez funkcji pomiarowej

Producent: Albert Browne Ltd
Chancery House
Rayns Way
Watermead Business Park
Syston
Leicester
LE7 1PF
UK

**Niepowtarzalny
numer rejestracyjny
(SRN):** -

**Upoważniony
przedstawiciel:** STERIS Ireland Ltd
IDA Business and Technology Park
Tullamore
County Offaly
R35 X865
Ireland

Produkt: **Steam Penetration Test Range**
See the next page of this declaration for product details.

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

Klasyfikacja: Klasa I, wyroby niesterylne, bez funkcji pomiarowej, zgodnie z regułą 1
z Załącznika VIII

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/EEG i 93/42/EEG. Produkt został poddany procedurom oceny zgodności zgodnie z rozporządzeniem MDR UE. Całość potwierdzającej to dokumentacji jest przechowywana u producenta.

**Nr certyfikatu(-ów)
ISO 13485:** Certificate Number MD 504862

**Rozpoczęcie
stosowania
oznakowania CE:** 2019-01-24

**Miejsce i data
wydania:** Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business
Park, Syston, Leicester, LE7 1PF, UK.
2021-10-14

Zatwierdzenie techniczne

Podpis:

Data: 5, 10, 21

Imię, nazwisko i tytuł: S. Hammond, Quality Director

Zatwierdzenie regulacyjne

Podpis:

13 Oct 2021

Data: / /

Imię, nazwisko i tytuł: L. Ballard, Regulatory & Quality Compliance Director



Produkt & Basic UDI-DI: **Bowie Dick Test Pack - 0724995LCPENBOWIEDICK23**
2310 Specific TST Bowie Dick Test Pack 121°C-124°C / 8 - 8.3 minutes
2352 Specific TST Bowie Dick Test Pack 134°C-137°C / 3.5 minutes
2385 Specific Sensor Chemical Indicator Test Sheet

Helix Load Test - 0724995LCPENHELIXLOAD37
3780 Specific TST Helix
3781 Specific TST Helix Starter Pack
2367 Euronda TST Helix Daily Steam Penetration Test 132°C - 137°C

Ball Type - 0724995LCPENBALLTYPER2
AB101 Porous & Hollow Steam Penetration Test 134°C-137°C / 3.5 minutes

Helix Load Test-NSK - 0724995LCNSKHELIXTESTEL
9900059 Helix Test for Steam Sterilizers

Top Dent Helix - 0724995LCTOPDENTHELIXGG
121184 Top Dent Helix Daily Steam Penetration Test 132°C - 137°C

W&H Helix - 0724995LCWHHELIXQ5
3804 TST Helix T800205X Daily Steam Penetration Test 132°C - 137°C
3805 TST Helix T801003X Daily Steam Penetration Test 132°C - 137°C

MELAG Load Test - 0724995LCMELCNTTESTLTC55
ME01080 MELAcontrol Helix



Declaração De Conformidade



pt

Dispositivos de Classe I não-estéril, sem medição

Fabricante: Albert Browne Ltd
Chancery House
Rayns Way
Watermead Business Park
Syston
Leicester
LE7 1PF
UK

Número de Registo -

Único (NRU):

Representante STERIS Ireland Ltd
Autorizado: IDA Business and Technology Park
Tullamore
County Offaly
R35 X865
Ireland

Produto: **Steam Penetration Test Range**
See the next page of this declaration for product details.

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

Classificação: Dispositivos de Classe I não-estéril, sem medição, de acordo com a Regra 1 do Anexo VIII

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.

Certificado(s) ISO Certificate Number MD 504862
13485 n.º:

Aposição da marca 2019-01-24
CE:

Local, data de Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business
emissão: Park, Syston, Leicester, LE7 1PF, UK.
2021-10-14

Aprovação técnica

Assinatura: 

Data: 5 / 10 / 21

Nome e cargo: S. Hammond, Quality Director

Aprovação de regularização

Assinatura: 

13 Oct 2021

Data: / /

Nome e cargo: L. Ballard, Regulatory & Quality Compliance Director



Produto & UDI-DI básico: **Bowie Dick Test Pack - 0724995LCPENBOWIEDICK23**
2310 Specific TST Bowie Dick Test Pack 121°C-124°C / 8 - 8.3 minutes
2352 Specific TST Bowie Dick Test Pack 134°C-137°C / 3.5 minutes
2356 Specific TST Bowie Dick Test Pack Single Use W&H 134°C-137°C / 3.5 minutes
6536 Specific TST Bowie Dick Test Pack Getinge 134°C-137°C / 3 - 3.5 minutes

Helix Load Test - 0724995LCPENHELIXLOAD37
3780 Specific TST Helix
3781 Specific TST Helix Starter Pack
2367 Euronda TST Helix Daily Steam Penetration Test 132°C - 137°C

Ball Type - 0724995LCPENBALLTYPER2
AB101 Porous & Hollow Steam Penetration Test 134°C-137°C / 3.5 minutes

Helix Load Test-NSK - 0724995LCNSKHHELIXTESTEL
9900059 Helix Test for Steam Sterilizers

Top Dent Helix - 0724995LCTOPDENTHELIXGG
121184 Top Dent Helix Daily Steam Penetration Test 132°C - 137°C

W&H Helix - 0724995LCWHHELIXQ5
3804 TST Helix T800205X Daily Steam Penetration Test 132°C - 137°C
3805 TST Helix T801003X Daily Steam Penetration Test 132°C - 137°C



Declarație De Conformitate



ro

Dispozitive nesterile, fără funcție de măsurare din Clasa I

Producător: Albert Browne Ltd
Chancery House
Rayns Way
Watermead Business Park
Syston
Leicester
LE7 1PF
UK

Număr unic de înregistrare (SRN): -

Reprezentant autorizat: STERIS Ireland Ltd
IDA Business and Technology Park
Tullamore
County Offaly
R35 X865
Ireland

Produs: **Steam Penetration Test Range**
See the next page of this declaration for product details.

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

Clasificare: Clasa I, dispozitive nesterile, fără funcție de măsurare, în conformitate cu Regula 1 din Anexa VIII

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.

ISO 13485 Certificate Number MD 504862
Certificat(e) CE nr.:

Data de început a marcajului CE: 2019-01-24

Locul, data eliberării: Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
2021-10-14

Aprobare tehnică

Semnătura: 

Data: 5 / 10 / 21

Numele și funcția: S. Hammond, Quality Director

Aprobare de reglementare

Semnătura: 

13 Oct 2021

Data: / /

Numele și funcția: L. Ballard, Regulatory & Quality Compliance Director



Declarație De Conformitate



ro

Produs & UDI- DI de bază: **Bowie Dick Test Pack - 0724995LCPENBOWIEDICK23**
2310 Specific TST Bowie Dick Test Pack 121°C-124°C / 8 - 8.3 minutes

Helix Load Test - 0724995LCPENHELIXLOAD37
2367 Euronda TST Helix Daily Steam Penetration Test 132°C - 137°C

MELAG Load Test - 0724995LCMELCNTTESTLC55
ME01080 MELAcontrol Helix

Ball Type - 0724995LCPENBALLTYPER2
AB101 Porous & Hollow Steam Penetration Test 134°C-137°C / 3.5 minutes

Trieda I zariadenia nesterilné, bez meracej funkcie

Výrobca: Albert Browne Ltd
Chancery House
Rayns Way
Watermead Business Park
Syston
Leicester
LE7 1PF
UK

Jedinečné registračné číslo (SRN – Single Registration Number): -
Oprávnený zástupca:

STERIS Ireland Ltd
IDA Business and Technology Park
Tullamore
County Offaly
R35 X865
Ireland

Výrobok: **Steam Penetration Test Range**
See the next page of this declaration for product details.

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

Klasifikácia: Trieda I zariadenia nesterilné, bez meracej funkcie podľa Pravidla 1 Prílohy VIII

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.

ISO 13485 Certifikát Certificate Number MD 504862
(y) č.:

Dátum začiatku označovania značkou zhody CE: 2019-01-24

Miesto, dátum vydania: Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
2021-10-14

Technické schválenie

Podpis: 

Dátum: 5 / 10 / 21

Meno a titul: S. Hammond, Quality Director

Regulačné schválenie

Podpis: 

Dátum: 13 Oct 2021
/ /

Meno a titul: L. Ballard, Regulatory & Quality Compliance Director



Výrobok & Základné číslo **Bowie Dick Test Pack - 0724995LCPENBOWIEDICK23**
UDI-DI: 2352 Specific TST Bowie Dick Test Pack 134°C-137°C / 3.5 minutes
2356 Specific TST Bowie Dick Test Pack Single Use W&H 134°C-137°C / 3.5 minutes
2385 Specific Sensor Chemical Indicator Test Sheet

Helix Load Test - 0724995LCPENHELIXLOAD37
3780 Specific TST Helix
3781 Specific TST Helix Starter Pack
2367 Euronda TST Helix Daily Steam Penetration Test 132°C - 137°C

Top Dent Helix - 0724995LCTOPDENTHELIXGG
121184 Top Dent Helix Daily Steam Penetration Test 132°C - 137°C

W&H Helix - 0724995LCWHHELIXQ5
3804 TST Helix T800205X Daily Steam Penetration Test 132°C - 137°C
3805 TST Helix T801003X Daily Steam Penetration Test 132°C - 137°C

MELAG Load Test - 0724995LCMELCNTTESTLC55
ME01080 MELAcontrol Helix

Ball Type - 0724995LCPENBALLTYPER2
AB101 Porous & Hollow Steam Penetration Test 134°C-137°C / 3.5 minutes



Nesterilni pripomočki brez merilne funkcije razreda I

Proizvajalec: Albert Browne Ltd
Chancery House
Rayns Way
Watermead Business Park
Syston
Leicester
LE7 1PF
UK

Enotna registrska številka (SRN) -

Pooblaščen zastopnik: STERIS Ireland Ltd
IDA Business and Technology Park
Tullamore
County Offaly
R35 X865
Ireland

Izdelek: **Steam Penetration Test Range**
See the next page of this declaration for product details.

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

Razvrstitev: Razred I – nesterilni pripomočki, brez merilne funkcije v skladu s pravilom 1 Priloge VIII

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.

Št. certifikata(-ov) ISO 13485: Certificate Number MD 504862

Začetek označevanja z oznako CE: 2019-01-24

Kraj, datum izdaje: Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
2021-10-14

Tehnično soglasje

Podpis:

Datum: 5. 10. 21

Ime in naziv: S. Hammond, Quality Director

Odobritev oddelka za regulativne zadeve

Podpis:

13 Oct 2021

Datum: / /

Ime in naziv: L. Ballard, Regulatory & Quality Compliance Director



Izjava O Skladnosti



sl

Izdelek & Bowie Dick Test Pack - 0724995LCPENBOWIEDICK23
Osnovni UDI- 2310 Specific TST Bowie Dick Test Pack 121°C-124°C / 8 - 8.3 minutes
DI: 2352 Specific TST Bowie Dick Test Pack 134°C-137°C / 3.5 minutes

Helix Load Test - 0724995LCPENHELIXLOAD37
2367 Euronda TST Helix Daily Steam Penetration Test 132°C - 137°C

MELAG Load Test - 0724995LCMELCNTTESTLC55
ME01080 MELAcontrol Helix



Klass I icke-steril, icke-mätande enheter

Tillverkare: Albert Browne Ltd
Chancery House
Rayns Way
Watermead Business Park
Syston
Leicester
LE7 1PF
UK

**Enskilt
registreringsnummer**

(SRN):

**Auktoriserad
representant:** STERIS Ireland Ltd
IDA Business and Technology Park
Tullamore
County Offaly
R35 X865
Ireland

Produkt: **Steam Penetration Test Range**
See the next page of this declaration for product details.

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

Klassificering: Klass I icke-sterila, icke-mätande enheter enligt regel 1 i bilaga VIII

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.

**ISO 13485 certifikat
#:** Certificate Number MD 504862

**Början av CE-
märkningen:** 2019-01-24

**Plats,
utgivningsdatum:** Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business
Park, Syston, Leicester, LE7 1PF, UK.
2021-10-14

Tekniskt godkännande

Underskrift:

Datum:

5 / 10 / 21

Namn och titel: S. Hammond, Quality Director

Reglerande godkännande

Underskrift:

13 Oct 2021

Datum:

/ /

Namn och titel: L. Ballard, Regulatory & Quality Compliance Director



Produkt & Grundläggande UDI-DI: **Bowie Dick Test Pack - 0724995LCPENBOWIEDICK23**
2352 Specific TST Bowie Dick Test Pack 134°C-137°C / 3.5 minutes
2356 Specific TST Bowie Dick Test Pack Single Use W&H 134°C-137°C / 3.5 minutes

Helix Load Test - 0724995LCPENHELIXLOAD37
3780 Specific TST Helix
3781 Specific TST Helix Starter Pack
2367 Euronda TST Helix Daily Steam Penetration Test 132°C - 137°C

Ball Type - 0724995LCPENBALLTYPER2
AB101 Porous & Hollow Steam Penetration Test 134°C-137°C / 3.5 minutes

Helix Load Test-NSK - 0724995LCNSKHHELIXTESTEL
9900059 Helix Test for Steam Sterilizers

Top Dent Helix - 0724995LCTOPDENTHELIXGG
121184 Top Dent Helix Daily Steam Penetration Test 132°C - 137°C

W&H Helix - 0724995LCWHHELIXQ5
3804 TST Helix T800205X Daily Steam Penetration Test 132°C - 137°C
3805 TST Helix T801003X Daily Steam Penetration Test 132°C - 137°C

MELAG Load Test - 0724995LCMELCNTTESTLC55
ME01080 MELAcontrol Helix