



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: Endoscope Test Devices 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: 2020-05-21

Place, Date of Issue: Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
2021-11-03

Quality Approval

Signature: [Handwritten Signature] Date: 27, 10, 21
Name and Title: S. Hammond, Quality Director

Regulatory Approval

Signature: [Handwritten Signature] Date: 03 Nov 2021
Name and Title: L. Ballard, Regulatory & Quality Compliance Director



Declaration of Conformity



en

Product & Basic UDI-DI: **Endoscope Test Devices - 0724995LCENDOMISLUMQM**
HX100 STF MIS-Lumen Test
HX101 STF MIS-Lumen Indicators
23.HX100 STF Mic Lumen Testkit, STF MIS Lumen Test, STF de Lumières CMI
23.HX101 STF Mic Indikatoren, STF MIS Indicators, STF CMI Indicateurs

Endoscope Test Devices - 0724995LCENDOHEXALUMNU
HX600 STF HexaLumen™ Automatic Endoscope Washer Disinfectant Test Kit
HX601 STF HexaLumen™ / HeptaLumen Automatic Endoscope Washer
Disinfectant Test Kit Indicators
HX602 STF HexaLumen™ / HeptaLumen Adaptor Kit
HX603 STF HexaLumen™ / HeptaLumen Adaptor Kit
HX604 STF HexaLumen™ / HeptaLumen Adaptor Kit
HX605 STF HexaLumen™ / HeptaLumen Adaptor Kit
HX700 STF HeptaLumen Automatic Endoscope Washer Disinfectant Test Kit
HX800 STF HexaLumen™ Endo-Test for ED-FLOW™ Automatic Endoscope
Washer Disinfectant Test Kit
HX900 STF HexaLumen™ Endo-Test for Wassenburg Medical AERs

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: Endoscope Test Devices 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:** 2020-05-21

**Místo, datum
vystavení:** Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business
Park, Syston, Leicester, LE7 1PF, UK.
2021-11-03

Technické schválení

Podpis:



Datum: 27. 10. 21

Jméno a titul: S. Hammond, Quality Director

Regulární souhlas

Podpis:



Datum: 03 Nov 2021

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



PROHLÁŠENÍ O SHODĚ



CS

Výrobek & Endoscope Test Devices - 0724995LCENDOMISLUMQM
Základní UDI- HX100 STF MIS-Lumen Test
DI: HX101 STF MIS-Lumen Indicators



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: **Endoscope Test Devices 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- 2020-05-21
Kennzeichnung:

Ort, Datum der Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business
Ausstellung: Park, Syston, Leicester, LE7 1PF, UK.
2021-11-03

Technische Zulassung

Unterschrift:

Datum: 27. 10. 21

Name und Titel: S. Hammond, Quality Director

Marktzulassung

Unterschrift:

03 Nov 2021

Datum: / /

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



Produkt & Endoscope Test Devices - 0724995LCENDOMISLUMQM

Basis-UDI- HX100 STF MIS-Lumen Test

DI: HX101 STF MIS-Lumen Indicators

23.HX100 STF Mic Lumen Testkit, STF MIS Lumen Test, STF de Lumières CMI

23.HX101 STF Mic Indikatoren, STF MIS Indicators, STF CMI Indicateurs

Endoscope Test Devices - 0724995LCENDOHEXALUMNU

HX600 STF HexaLumen™ Automatic Endoscope Washer Disinfector Test Kit

HX601 STF HexaLumen™ / HeptaLumen Automatic Endoscope Washer Disinfector Test Kit Indicators

HX700 STF HeptaLumen Automatic Endoscope Washer Disinfector Test Kit

HX800 STF HexaLumen™ Endo-Test for ED-FLOW™ Automatic Endoscope

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: Endoscope Test Devices 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: 2020-05-21

Sted, udstedelsesdato: Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
2021-11-03

Teknisk godkendelse

Underskrift:  **Dato:** 27, 10, 21

Navn og titel: S. Hammond, Quality Director

Lovmæssig godkendelse

Underskrift:  **Dato:** 03 Nov 2021

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



Produkt & Endoscope Test Devices - 0724995LCENDOHEXALUMNU

Basal UDI- HX600 STF HexaLumen™ Automatic Endoscope Washer Disinfector Test Kit

DI: HX601 STF HexaLumen™ / HeptaLumen Automatic Endoscope Washer Disinfector Test Kit
Indicators

HX700 STF HeptaLumen Automatic Endoscope Washer Disinfector Test Kit



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:** **Endoscope Test Devices 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) ISO 13485: Certificate Number MD 504862

Inicio de la marca CE: 2020-05-21

Lugar y fecha de publicación: Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
2021-11-03

Aprobación técnica

Firma:

Fecha: 27, 10, 21

Nombre y cargo: S. Hammond, Quality Director

Aprobación reglamentaria

Firma:

03 Nov 2021

Fecha: / /

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



Producto Endoscope Test Devices - 0724995LCENDOHEXALUMNU
& UDI-DI HX600 STF HexaLumen™ Automatic Endoscope Washer Disinfector Test Kit
básico: HX601 STF HexaLumen™ / HeptaLumen Automatic Endoscope Washer Disinfector Test Kit
Indicators
HX700 STF HeptaLumen Automatic Endoscope Washer Disinfector Test Kit
HX800 STF HexaLumen™ Endo-Test for ED-FLOW™ Automatic Endoscope

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: **Endoscope Test Devices 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:** 2020-05-21

**Paikka,
antamispäivämäärä:** Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business
Park, Syston, Leicester, LE7 1PF, UK.
2021-11-03

Tekninen hyväksyntä

Allekirjoitus:



Päivämäärä:

27, 10, 21

Nimi ja titteli:

S. Hammond, Quality Director

Säätelyn mukainen hyväksyntä

Allekirjoitus:



03 Nov 2021

Päivämäärä:

1 1

Nimi ja titteli:

L. Ballard, Regulatory & Quality Compliance Director



Tuote & Perustaso **Endoscope Test Devices - 0724995LCENDOHEXALUMNU**
Perustaso HX600 STF HexaLumen™ Automatic Endoscope Washer Disinfector Test Kit
UDI-DI: HX601 STF HexaLumen™ / HeptaLumen Automatic Endoscope Washer Disinfector Test Kit Indicators
HX700 STF HeptaLumen Automatic Endoscope Washer Disinfector Test Kit



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: Endoscope Test Devices 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:** 2020-05-21

**Lieu, date de
délivrance:** Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business
Park, Syston, Leicester, LE7 1PF, UK.
2021-11-03

Approbation technique

Signature:  **Date:** 27, 10, 21

Nom et titre: S. Hammond, Quality Director

Approbation réglementaire

Signature:  **Date:** 03 Nov 2021
/ /

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



Déclaration de Conformité



fr

Produit & IUD-ID de base: **Endoscope Test Devices - 0724995LCENDOMISLUMQM**
HX100 STF MIS-Lumen Test
HX101 STF MIS-Lumen Indicators
23.HX100 STF Mic Lumen Testkit, STF MIS Lumen Test, STF de Lumières CMI
23.HX101 STF Mic Indikatoren, STF MIS Indicators, STF CMI Indicateurs

Endoscope Test Devices - 0724995LCENDOHEXALUMNU
HX600 STF HexaLumen™ Automatic Endoscope Washer Disinfector Test Kit
HX601 STF HexaLumen™ / HeptaLumen Automatic Endoscope Washer Disinfector Test Kit Indicators
HX700 STF HeptaLumen Automatic Endoscope Washer Disinfector Test Kit
HX800 STF HexaLumen™ Endo-Test for ED-FLOW™ Automatic Endoscope

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: **Endoscope Test Devices Range**
See the next page of this declaration for product details.

**Alapvető egyedi
eszközazonosító
(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: 2020-05-21

**Kiadás
helye/időpontja:** Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business
Park, Syston, Leicester, LE7 1PF, UK.
2021-11-03

Műszaki Engedély

Aláírás: 

Dátum: 27. 10. 21

Név és cím: S. Hammond, Quality Director

Hatósági engedély

Aláírás: 

03 Nov 2021

Dátum: / /

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



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

Endoscope Test Devices - 0724995LCENDOHEXALUMNU

HX600 STF HexaLumen™ Automatic Endoscope Washer Disinfector Test Kit

HX601 STF HexaLumen™ / HeptaLumen Automatic Endoscope Washer Disinfector
Test Kit Indicators

HX700 STF HeptaLumen Automatic Endoscope Washer Disinfector Test Kit



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: Endoscope Test Devices 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: 2020-05-21

Luogo e data di rilascio: Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
2021-11-03

Approvazione tecnica

Firma:  **Data:** 27, 10, 21

Nome e qualifica: S. Hammond, Quality Director

Approvazione regolatoria

Firma:  **Data:** 03 Nov 2021
/ /

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



Prodotto & UDI-DI di base: **Endoscope Test Devices - 0724995LCENDOHEXALUMNU**
HX600 STF HexaLumen™ Automatic Endoscope Washer Disinfector Test Kit
HX601 STF HexaLumen™ / HeptaLumen Automatic Endoscope Washer Disinfector Test Kit Indicators
HX700 STF HeptaLumen Automatic Endoscope Washer Disinfector Test Kit
HX800 STF HexaLumen™ Endo-Test for ED-FLOW™ Automatic Endoscope



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: Endoscope Test Devices 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 apliecinātie dokumenti ir saglabāti ražotāja objektos.

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

CE zīmes uzlikšanas datums: 2020-05-21

Izdošanas vieta un datums: Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
2021-11-03

Tehniskais apstiprinājums

Paraksts:

Datums: 27, 10, 21

Vārds, uzvārds un amata nosaukums:

S. Hammond, Quality Director

Apstiprinājums par atbilstību prasībām

03 Nov 2021

Paraksts:

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



ATBILSTĪBAS DEKLARĀCIJA



iv

Izstrādājums & Endoscope Test Devices - 0724995LCENDOMISLUMQM
Pamata UDI-DI: HX100 STF MIS-Lumen Test
HX101 STF MIS-Lumen Indicators

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: Endoscope Test Devices 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 bedrijfsspan van de producent bewaard.

**ISO 13485-
certificaat/certificaten** Certificate Number MD 504862

nr.:
**Ingangsdatum CE-
markering:** 2020-05-21

**Plaats, datum van
uitgifte:** Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business
Park, Syston, Leicester, LE7 1PF, UK.
2021-11-03

Technische goedkeuring

Handtekening:  **Datum:** 27, 10, 21

Naam en functie: S. Hammond, Quality Director

Interne goedkeuring

Handtekening:  **Datum:** 03 Nov 2021

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



Product & Basic UDI-DI: **Endoscope Test Devices - 0724995LCENDOMISLUMQM**
HX100 STF MIS-Lumen Test
HX101 STF MIS-Lumen Indicators

Endoscope Test Devices - 0724995LCENDOHEXALUMNU
HX600 STF HexaLumen™ Automatic Endoscope Washer Disinfector Test Kit
HX601 STF HexaLumen™ / HeptaLumen Automatic Endoscope Washer Disinfector Test Kit Indicators
HX700 STF HeptaLumen Automatic Endoscope Washer Disinfector Test Kit



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: Endoscope Test Devices 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/EWG i 93/42/EWG. 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: 2020-05-21

Miejsce i data wydania: Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
2021-11-03

Zatwierdzenie techniczne

Podpis:

Data: 27, 10, 21

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

Zatwierdzenie regulacyjne

Podpis:

03 Nov 2021

Data: / /

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



Deklaracja Zgodności



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Produkt & Endoscope Test Devices - 0724995LCENDOMISLUMQM
Basic UDI-DI: HX100 STF MIS-Lumen Test
HX101 STF MIS-Lumen Indicators

Endoscope Test Devices - 0724995LCENDOHEXALUMNU
HX600 STF HexaLumen™ Automatic Endoscope Washer Disinfector Test Kit
HX601 STF HexaLumen™ / HeptaLumen Automatic Endoscope Washer Disinfector Test Kit
Indicators
HX700 STF HeptaLumen Automatic Endoscope Washer Disinfector Test Kit



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

Produto: Endoscope Test Devices 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 13485 n.º: Certificate Number MD 504862

Aposição da marca CE: 2020-05-21

Local, data de emissão: Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
2021-11-03

Aprovação técnica

Assinatura:

Data: 27, 10, 21

Nome e cargo: S. Hammond, Quality Director

Aprovação de regularização

Assinatura:

03 Nov 2021

Data: / /

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



Produto & UDI-DI básico: **Endoscope Test Devices - 0724995LCENDOHEXALUMNU**
HX600 STF HexaLumen™ Automatic Endoscope Washer Disinfector Test Kit
HX601 STF HexaLumen™ / HeptaLumen Automatic Endoscope Washer Disinfector Test Kit Indicators
HX700 STF HeptaLumen Automatic Endoscope Washer Disinfector Test Kit
HX800 STF HexaLumen™ Endo-Test for ED-FLOW™ Automatic Endoscope

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: **Endoscope Test Devices 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: 2020-05-21

Kraj, datum izdaje: Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
2021-11-03

Tehnično soglasje

Podpis: 

Datum: 27. 11. 21

Ime in naziv: S. Hammond, Quality Director

Odobritev oddelka za regulativne zadeve

Podpis: 

03 Nov 2021

Datum: / /

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



Izjava O Skladnosti



sl

Izdelek & Endoscope Test Devices - 0724995LCENDOMISLUMQM
Osnovni UDI- HX100 STF MIS-Lumen Test
DI: HX101 STF MIS-Lumen Indicators

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: **Endoscope Test Devices 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:** 2020-05-21

**Plats,
utgivningsdatum:** Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business
Park, Syston, Leicester, LE7 1PF, UK.
2021-11-03

Tekniskt godkännande

Underskrift:



Datum:

27, 10, 21

Namn och titel:

S. Hammond, Quality Director

Reglerande godkännande

Underskrift:



03 Nov 2021

Datum:

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Namn och titel:

L. Ballard, Regulatory & Quality Compliance Director



Produkt & Grundläggande UDI-DI: **Endoscope Test Devices - 0724995LCENDOMISLUMQM**
HX100 STF MIS-Lumen Test
HX101 STF MIS-Lumen Indicators

Endoscope Test Devices - 0724995LCENDOHEXALUMNU
HX600 STF HexaLumen™ Automatic Endoscope Washer Disinfector Test Kit
HX601 STF HexaLumen™ / HeptaLumen Automatic Endoscope Washer Disinfector Test Kit Indicators
HX700 STF HeptaLumen Automatic Endoscope Washer Disinfector Test Kit
HX800 STF HexaLumen™ Endo-Test for ED-FLOW™ Automatic Endoscope