



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(s) #:** Certificate Number MD 504862

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.
2020-11-18

Quality Approval

Signature: 
Name and Title: S. Hammond, Quality Director

Date: 17 / 11 / 2020

Regulatory Approval

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

Date: 17 Nov 2020
/ /

SCS-148-TM-005 Declaration of Conformity Template (EU MDR) – Class I non-sterile, non-measuring. Version 2

Product: Steam Penetration Test Range

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
2365 Specific TST Bowie Dick Test Pack, Prestige Medical Advance Vacuum 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
3780 Specific TST Helix
3781 Specific TST Helix Starter Pack
6536 Specific TST Bowie Dick Test Pack Getinge 134°C-137°C / 3 - 3.5 minutes
9900059 Helix Test for Steam Sterilizers
AB101 Porous & Hollow Steam Penetration Test 134°C-137°C / 3.5 minutes

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
2365 Specific TST Bowie Dick Test Pack, Prestige Medical Advance Vacuum 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

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