



Declaration of Conformity

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 Page 2 of this declaration for product details.

Basic UDI-DI: See Page 2 of this declaration for Basic UDI-DI details.


Classification: Class I non-sterile, non-measuring according to Rule 1 of Annex VIII of MDR
2017/745

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

Notified Body: BSI Certified for ISO 13485:2016, Certificate Number MD 504862.


EC Certificate(s) #: N/A
Start of CE Marking: 8th October 2018
Place, Date of Issue: Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
Issued 2020-04-28

Quality Approval

Signature:  **Date:** 28/4/2020

Name and Title: S. Hammond, Quality Director

Regulatory Approval

Signature:  **Date:** 29 April 2020

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



Declaration of Conformity

Product: 2310 TST Bowie Dick Type Test Pack 121°C / 8 minutes
2352 TST Single Use Bowie Dick Test Pack
2356 Single Use W & H Bowie Dick Test Pack
2358 TST Bowie Dick Test Pack Eschmann
2365 Prestige Century 2 Vacuum Bench Top Bowie Dick Packs
2368 TST Single Use Euronda Bowie Dick Test Pack
2385 UK Sensor Sheet
3780 TST Helix
3781 TST Helix Starter Pack
6536 Getinge Bench Top Bowie Dick Test Pack
AB101 Porous & Hollow Steam Penetration Test

Basic UDI-DI Bowie Dick Test Pack - 0724995LCPENBOWIEDICK23
2310 TST Bowie Dick Type Test Pack 121°C / 8 minutes
2352 TST Single Use Bowie Dick Test Pack
2356 Single Use W & H Bowie Dick Test Pack
2358 TST Bowie Dick Test Pack Eschmann
2365 Prestige Century 2 Vacuum Bench Top Bowie Dick Packs
2368 TST Single Use Euronda Bowie Dick Test Pack
2385 UK Sensor Sheet
6536 Getinge Bench Top Bowie Dick Test Pack

Helix Load Test - 0724995LCPENHELIXLOAD37
3780 TST Helix
3781 TST Helix Starter Pack

Ball Type - 0724995LCPENBALLTYPER2
AB101 Porous & Hollow Steam Penetration Test