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: S. Hammond **Date:** 17 / 11 / 2020

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

Regulatory Approval

Signature: L Ballard **Date:** 17 Nov 2020 / /

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

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

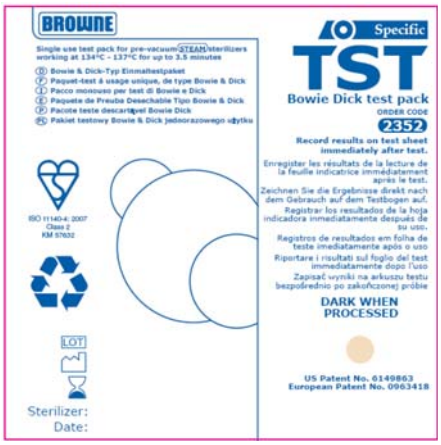
Helix Load Test - 0724995LCPENHELIXLOAD37
3780 Specific TST Helix
3781 Specific TST Helix Starter Pack

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

Product Data Sheet
2352

Product Description	The TST Single Use Bowie Dick Test is designed as a daily test of the efficacy of air removal in a porous load steam sterilizer working at 134- 137˚C. It consists of a number of specially selected sheets of barrier material and a chemical indicator sheet. The whole pack is wrapped in steam sterilizable paper. The indicator sheet inside the pack is sensitive to **T**ime, **S**team and **T**emperature (TST). A shipper case contains 20 Bowie Dick tests and includes instruction leaflet, lot and expiration data. This product bears the BSI Kitemark. This provides assurance that samples are regularly subjected to rigorous, independent testing by British Standards Institution to ensure that they comply with stringent standards for safety, product performance, and reliability. In addition, the Kitemark also means that the quality systems of the manufacturing facility where this Bowie Dick is made are systematically assessed. The Kitemark is therefore Albert Browne's commitment towards maintaining the highest possible standards.



Specification	Colour changes from yellow to completely blue / purple if rapid and even steam penetration has occurred at 134-137ºC for a holding period of up to 3.5 minutes.
Applicable standards	ISO 11140-4 Class 2
Product Size	124mm x 124mm
Packaging	Primary case Contents: 20Test Packs Size 325mm x 256mm x 126mm Weight: 6.3kg Gross
Recommended Storage	Cool, dark, dry conditions before and after use: 0 - 30˚C 30 – 60 % RH
Shelf Life	36 months from date of manufacture
Active Components	Each indicator, which is the indicating medium, contains 0.7mg dyes and 0.7mg reagents. None of the substances used in the formulation are known carcinogens, nor do they contain any heavy metals. The component chemicals are potentially irritant. Being fully encapsulated, this should present no occasion for contact with the chemical components. If however, contact is made due to breakdown of the encapsulation, wash the skin with soap and water. If ingested wash out the mouth thoroughly and give plenty of water to drink. None of the components are of animal origin, hence to the best of our knowledge is free of TSE (Transmissible Spongiform Encephalopathy) agents.
Safe Usage	The indicator and packaging contain no added heavy metals, no known carcinogens, and no added rubber latex. The indicator is considered safe when used under normal conditions. The TST Single Use Bowie Dick Test is designed to be used in high vacuum steam autoclaves. When used in such devices no inherent hazards are likely to present themselves. When used as intended, the indicator does not release any substances known to be toxic in sufficient quantities to cause a health hazard, during or after the sterilization process for which it is designated, in accordance with ISO 11140-1:2005, 5.9
Disposal	Treat unwanted indicators and packaging in the same way as normal paper waste

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ISO 9001
FM26021
ISO 13485
MD504862

ISO 11140-4:2005 Class 2
KM57632