



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**
2356 Specific TST Bowie Dick Test Pack Single Use W&H 134°C-137°C /
3.5 minutes
3804 TST Helix T800205X Daily Steam Penetration Test 132°C - 137°C
3805 TST Helix T801003X Daily Steam Penetration Test 132°C - 137°C

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

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

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.
2021-08-04

Quality Approval

Signature: 

Date: 5 / 8 / 21

Name and Title: S. Hammond, Quality Director