



Declaration of Conformity

 STERIS

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: **Process Challenge Device Indicators 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: 2019-06-18

Place, Date of Issue: Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, UK.
2020-09-23

Quality Approval

Signature:  **Date:** 23, 9, 2020
Name and Title: S. Hammond, Quality Director

Regulatory Approval

Signature:  **Date:** 23, Sept, 2020
Name and Title: L. Ballard, Regulatory & Quality Compliance Director

Product: Process Challenge Device Indicators Range

2445A – Specific Formaldehyde Loadcheck

3777 – Specific TST Loadcheck 134°C / 4 minutes & 121°C / 12 minutes

3778 – Specific TST Loadcheck 134°C / 5.3 minutes & 121°C / 15 minutes

3779 – Specific TST Loadcheck 134°C / 7 minutes & 121°C / 20 minutes

3783 – Specific TST Loadcheck 134°C / 3.5 minutes

AB123 - Spiral Load Check

Basic UDI-DI: Formaldehyde Process Challenge Device - 0724995LCPCDIFORMHYDETW

2445A – Specific Formaldehyde Loadcheck

Steam Process Challenge Device – 0724995LCPCDISTEAMT4

3777 – Specific TST Loadcheck 134°C / 4 minutes & 121°C / 12 minutes

3778 – Specific TST Loadcheck 134°C / 5.3 minutes & 121°C / 15 minutes

3779 – Specific TST Loadcheck 134°C / 7 minutes & 121°C / 20 minutes

3783 – Specific TST Loadcheck 134°C / 3.5 minutes

AB123 - Spiral Load Check