



## Declaration of Conformity



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### 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 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:** 2019-01-10

**Place, Date of Issue:** Albert Browne Ltd, Chancery House, Rayns Way, Watermead Business  
Park, Syston, Leicester, LE7 1PF, UK.  
2021-02-03

#### Quality Approval

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

**Date:** 3, 2, 21

#### Regulatory Approval

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

**Date:** 03 Feb 2021  
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SCS-148-TM-005 Declaration of Conformity Template (EU MDR) – Class I non-sterile, non-measuring. Version 2



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**Product & Basic** Ethylene Oxide indicators - 0724995LCPIETHYOXIND95  
2420 Ethylene Oxide Integrating Indicator  
**UDI-DI:** 2421 Process Ethylene Oxide Indicator Spots  
2563 BX250 Multi Variable Ethylene Oxide Sterilization Indicator

**Formaldehyde indicators – 0724995LCPIFORMHYDINDBK**  
2401 Multi-Variable Formaldehyde Multi-Variable Control Indicator  
2402 Process Formaldehyde Indicator Spots

**Gamma Radiation indicators - 0724995LCPIGAMMARADINQT**  
3301 Process Gamma Check Indicator Spots

**Peracetic Acid liquid chemical sterilant indicators - 0724995LCVERFYPERACIDK4**  
LCC023 Verify® Chemical Indicator for SYSTEM 1 EXPRESS/PLUS using S40™ Sterilant Concentrate  
LCC024 Verify® Chemical Indicator for SYSTEM 1™ using S20™ Sterilant Concentrate  
PCC029 Verify® Process Indicator for Reliance™ EPS Endoscope Processing System

**Steam and EO Combination indicators - 0724995LCVERFYSTEORCUL**  
RK019 Verify® Steam and EO Load Record Card

**Steam indicators - 0724995LCPISTEAMINDZK**  
2551 Multi Variable MVI Steam Sterilization Indicator  
5008-400 Steam Process Indicator Labels 75mm x 123mm

**Steam indicators - 0724995LCPISTCNTRLINTE**  
2302 Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2317 Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2340 Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
2341 Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
2342 Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins  
2375 Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins and 121 °C / 12 mins  
3103 Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3104 Emulating TST Control™ Cycle Verification Indicator 134 °C / 4 mins Self-adhesive  
3105 Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins Self-adhesive  
3107 Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins Self-adhesive  
3702 Emulating TST Control™ Cycle Verification Indicator 134 °C / 9 mins  
3706 Emulating TST Control™ Cycle Verification Indicator 134 °C / 18 mins  
3725 Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 mins Self Adhesive  
3726 Emulating TST Control™ Cycle Verification Indicator 134 °C / 5.3 mins and 121 °C / 15 mins Self Adhesive  
3727 Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins Self-adhesive  
3737 Emulating TST Control™ Spot with Sterilizer Record Book 121 °C / 15 mins  
3739 Emulating TST Control™ Spot with Sterilizer Record Book 134 °C / 3.5 mins  
3760 Emulating TST Control™ Cycle Verification Indicator 134 °C / 7 mins and 121 °C / 20 min  
5006 Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins  
5006-800 Emulating TST Control™ Cycle Verification Indicator Multi-part label 134 °C / 3.5 mins  
5017 Emulating TST Control™ Cycle Verification Indicator 134 °C / 3.5 mins  
6610300 TST Patient Record Card 134 °C / 5.3 mins

**Steam indicators - 0724995LCPICNTRLTUBE6K**  
7301 Sterilizer Control Tubes Type 1 (Black Spot) 121 °C / 15 min  
7302 Sterilizer Control Tubes Type 2 (Yellow Spot) 134 °C / 3 min  
7303 Sterilizer Control Tubes Type 3 (Green Spot) 160 °C / 60 min  
7304 Sterilizer Control Tubes Type 4 (Blue Spot) 180 °C / 12 min  
7305 Sterilizer Control Tubes Type 5 (White Spot) 160 °C / 120 min, 170 °C / 65 min, 180 °C / 35 min

**Steam Indicators - 0724995LCPIVFYSIXCESSTK**  
PCC035 SixCess™ 134C 5.3 Min / 121C 15 Min Indicadores / Indicator / Indicadore



## Declaration of Conformity



### **Steam indicators - 0724995LCPIBROWNESMIND9**

3100 Browne Steam Integrating Indicator Type 5

3101 Browne Steam Integrating Indicator Type 5

3785-24 Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm - Italian

3789-24 Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm - English

3794-24 Documentation System Label for use with BROWNE 3 line label gun 26mm x 25mm – Portuguese

5003 Browne Steam 2 Part Pack Control Label

### **Vaporised Hydrogen Peroxide indicators – 0724995LCPIVHPINDEC**

2501 Multi Variable VAPOUR STRIP Multi-Variable Indicator for Vaporised Hydrogen Peroxide

RK053 Verdoc™ HPI Vaporized VH202 Record Card with Process Indicator

### **Vaporised Hydrogen Peroxide indicators – 0724995LCVERIFYVHPINDNW**

PCC044 Verify® Control Quimico VH202 / Vaporized VH202 Chemical Indicator / Indicador Quimico

Vaporizado VH202

PCC057 Verify® HPI Vaporized VH202 Process Indicator Adhesive Label

PCC062 Verify® HPI Chemical Indicator

### **Vaporised Hydrogen Peroxide indicators – 0724995LCCELERITYHPCIST**

PCC074 Celerity™ HP Chemical Indicator / Indicador Quimico HP

PCC075 Celerity™ HP Chemical Indicator / Indicador Quimico HP

PCC078 Celerity™ Vaporized VH202 Process Indicator Adhesive Label / Etiqueta Adhesiva Indicadora

De Proceso Vaporized VH202

### **Dry Heat Indicators - 0724995LCPIDRYHEATIND7F**

2470 Emulating Des-Check Low Temperature Disinfection Indicator 93°C / 10min

2471 Emulating Des-Check Low Temperature Disinfection Indicator 90°C / 5min