



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



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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