

EC Declaration of Conformity

Technical File - Kaltostat {WTTF-001, PR/DL20-033}

Manufacturer Name: ConvaTec Limited,
 Address: First Avenue, Deeside Industrial Park, Deeside, Flintshire, CH5 2NU
 United Kingdom

This Declaration is made under the sole responsibility of the manufacturer, ConvaTec Limited, who herewith declares that the attached list of mentioned product conforms to the applicable essential requirements and provisions of Medical Devices Directive 93/42/EEC, as amended by Directive 2007/47/EC) concerning medical devices.

Product Name	Trade/ Brand Name(s): Kaltostat, Calcium/Sodium Alginate High G80:20 Dressing – Sterile
Product Codes	Applicable product codes are listed in the attached.
Classification and Rule (Include Sterility / Measuring if applicable)	Class IIb Sterile, as defined by Rule 4, laid down in Annex IX of the EC Medical Device Directive (93/42/EEC)
Conformity Assessment Route	Annex II
Notified Body Name, Identification number Address	The British Standards Institute (BSI) 2797 BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands
Authorised Representative in the European Community	Unomedical A/S, Aaholmvej 1-3, Osted, 43230, Lejre, Denmark
(QA/EC) Certification Number	ISO 13485:2016 & EN ISO 13485:2016 Certificate Number MD 670405 QA Certificate Number 00364
GMDN Code and Term title	43186 - Exudate-absorbent dressing, hydrophilic-gel
Harmonised Standards Applied:	EN ISO 13485:2012, EN ISO 10993:2003/9, EN ISO 14971:2012, EN ISO 13726:2002, EN1041: 2008, EN13726, EN ISO 11137-1:2006, EN ISO 11137-2:2013, EN ISO 11137-3:2006, ISO 15223-1:2012, BS EN ISO 14155:2003, BS EN 11607-1:2009, ISO 11607-2:2012, BS EN ISO 14644:2015, BS EN 62366:2008

Issued in Deeside, UK.

Signed for and on behalf of ConvaTec Limited

Name: Rebecca Sheridan



Date: 19/MAR/2019

Senior Director, Advanced Wound Care QARAC

Kaltostat, PR/DL20-033

Trade/Brand Name: Kaltostat, Calcium/Sodium Alginate High G80:20 Dressing - Sterile

Product Codes	Product Description, Dressing Size & Pack quantity
168215	KALTOSTAT, 15cmx25cm, 10/pack
168214	KALTOSTAT, 10cmx20cm, 10/pack
168212	KALTOSTAT, 7.5cmx12cm, 10/pack
168219	KALTOSTAT, 5cmx30cm, 10/pack
168210	KALTOSTAT, 5cmx5cm, 10/pack
168117	KALTOSTAT, 2g Rope, 5/pack
168101	KALTOSTAT, 10cmx10cm, 5/pack