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	Class IIb, 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-NL) 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, 4320, Lejre, Denmark
(QA/EC) Certification Number	ISO 13485:2016 & EN ISO 13495:2016 Certification Number MD 670405 QA Certificate Number 00364
GMDN Code and Term title	43186- Exudate- absorbent dressing, hydrophilic-gel
Harmonised Standards Applied: **OJ 2017/C 389/03 apply until 30 September 2021)**	EN ISO 13485: 2016 - QMS - Requirements for regulatory purposes. EN 13726-1:2002- Test methods for primary wound dressings - Part 1: Aspects of absorbency EN 13726-2:2002- Test methods for primary wound dressings - Part 2: Moisture vapour transmission rate of permeable film dressings EN ISO 11137-1:2015- Sterilization of health care products. Radiation. Requirements for development, validation and routine control of a sterilization process for medical devices EN ISO 11137-2:2015 - Sterilization of health care products. Radiation. Establishing the sterilization dose EN ISO 15223-1: 2016- Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

ConvaTec Limited Registered No. 1309639
Registered Office: ConvaTec Limited, GDC First Avenue, Deeside Industrial Park, Deeside, Flintshire CH5 2NU

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	EN 62366:1-2015 - Application of usability engineering to medical devices EN ISO 14155:2011 - Clinical investigation of medical devices for human subjects - Good Clinical Practice
Applicable, Reference Standards (ISO, BS EN)	EN ISO 14155:2011 - Clinical investigation of medical devices for human subjects - Good Clinical Practice BS EN ISO 10993-4: 2017 - Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood BS EN ISO 10993-6: 2016 - Biological evaluation of medical devices. Tests for local effects after implantation BS EN ISO 10993-10: 2013 - Biological evaluation of medical devices. Tests for irritation and skin sensitization BS EN ISO 10993-12: 2012 - Biological evaluation of medical devices. Tests for local effects after implantation BS EN ISO 10993-17: 2009 - Biological evaluation of medical devices. Establishment of allowable limits for leachable substances EN ISO 10993-18: 2009 - Biological evaluation of medical devices – Part 18: Chemical characterization of materials BS EN ISO 10993-1:2020 part 1 : Evaluation and Testing within a Risk Management Process. EN ISO 14971:2019 Application of Risk Management to Medical. Devices EN 1041:2008+A1:2013- Information supplied by the Manufacturer of Medical Devices EN ISO 14644-1:2015 Cleanrooms and associated controlled environments Part 1: Classification of air cleanliness by particle concentration EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes EN ISO 10993-1: 2009/AC:2010. ISO 10993-1:2018 - Biological Evaluation of Medical Devices - Part 1; Evaluation and Testing within a Risk Management Process EN ISO 10993-3: 2014 - Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity EN ISO 10993-4: 2009 - Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood EN ISO 10993-5: 2009 - Biological Evaluation of Medical Devices – Part 5; Tests for In-Vitro Cytotoxicity

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	EN ISO 10993-11: 2018 - Biological evaluation of medical devices — Part 11: Tests for systemic toxicity ISO 10993-10:2010 Biological evaluation of medical devices. Part 10: Tests for irritation and skin sensitization ISO 10993-6:2016 - Biological evaluation of medical devices. Tests for local effects after implantation ISO 10993-18:2020 - Biological evaluation of medical devices. Chemical Characterisation of medical devices within a risk management process ISO 10993-17:2002 - Biological evaluation of medical devices. Part 17: Establishment of allowable limits for leachable substances

Issued in Deeside, UK.
Signed for and on behalf of ConvaTec Limited

Name: Date: 15 May 2021
Gary Barrett (dd/mmm/yyyy)
Vice President, Regulatory Affairs

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

SAP Code	Product Description	ICC
1226630	KALTOSTAT , 15cm X 25cm 10/Pack	168215
1226579	KALTOSTAT , 10cm X 20cm 10/Pack	168214
1226681	KALTOSTAT , 7.5cm X 12cm 10/Pack	168212
1226636	KALTOSTAT , 30cm X 60cm 10/Pack	168219
1203730, 1203783	KALTOSTAT , 5cm X 5cm 10/Pack	168210
1213260, 1213285	KALTOSTAT , 2g Rope 5/Pack	168117
1226549	KALTOSTAT , 10cm X 10cm 5/Pack	168101

History Page

Issue number	Date	Comment
1	30 Jan 1996	Original Issue
2	15 Jan 1998	Additional of specification number
3	13 Aug 1998	Addition of Kaltostat Fortex
4	22 Oct 2002	New format to certificate
5	13 Nov 2003	Change of signatorty to conform with SOP-706
6	31 May 2006	Re-issue to remove references to discontinued quality standard
7	01 Aug 2008	New letterheaded paper
8	06 Jul 2010	Technical File updated in line with PI changes
9	15 Oct 2010	Technical File update to incorporate new IFU version
10	16 May 2011	Technical File update to incorporate new IFU version
11	10 Feb 2012	New alginate raw material qualified
12	15 Feb 2012	New Film/film primary packaging
13	30 Jan 2017	New format for Declaration of Conformity
14	23 Feb 2018	Technical File update to incorporate changes
15	17 May 2018	Technical File update with new risk and hazard analysis
16	19 Mar 2019	Change of Notifed Body from BSI UK to BSI Netherlands
17	20 Aug 2020	Re-issue for standards and file remediation
18	12 Nov 2020	Update to EC Rep address
19	18 May 2021	Correction to Issue and Date

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