

EC Declaration of Conformity

Technical File WTTF-011

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): DuoDERM Hydroactive Gel, DuoDERM Hydrogel, GranuGEL Hydrocolloid Gel Varihesive Hydrogel and Applicator Nozzles
Product Codes	Applicable product codes are listed in the attached.
Classification and Rule (Include Sterility / Measuring if applicable)	Class IIb, as defined in Article 1 and based on 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, 4320, Lejre, Denmark
(QA) Certification Number	CE 00364
GMDN Code and Term title	43186, Exudate absorbent dressing, hydrophillic gel-forming

Issued in Deeside, UK.

Signed for and on behalf of ConvaTec Limited



Name: _____

Gary Barrett
Vice President, Regulatory Affairs

Date: July 4 2022

WTTF-011 DuoDERM Gel and Applicator Nozzles

Trade/Brand Name: DuoDERM Hydroactive Gel, DuoDERM Hydrogel, GranuGEL Hydrocolloid Gel Varihesive Hydrogel and Applicator Nozzles

ICC Code	Description	Quantity	Specifications	SAP
187990	15g tubes without nozzles	10	PR20-011	1021844 (DuoDERM) 1024875 (DuoDERM) 1024878 (DuoDERM) 1031631 (GranuGel)
401802	15g tubes with nozzles	10	PR20-011	1023066 (GranuGel) 1049998 (Varihesive) 1050013 (Varihesive) 1050022 (DuoDERM) 1103466 (Varihesive) 1100164 (GranuGel)
403700	15g tubes with nozzles	5	PR20-011	1049997 (Varihesive) 1050012 (Varihesive) 1050016 (DuoDERM) 1103575 (Varihesive)
403701	15g tube without nozzle	1	PR20-011	1050020 (DuoDERM) 1050021 (DuoDERM)

WTTF-011 DuoDERM Gel and Applicator Nozzle

History Page

Issue Number	Date	Comment
1	1 st September 1994	First issue
2	20 th July 2000	New format certificate
3	13 th November 2003	Amendment to product name to match specification and change of signatory to conform with SOP 706
4	31 st May 2006	Re-issued to remove references to discontinued quality standard
5	1 st August 2008	New letter headed paper
6	8 th September 2008	Updated ER Checklist Updated Section 12 (labelling) Updated Section 13 to reflect Annex C in ISO14971:2007
7	17 th September 2012	Updated ER Checklist Updated Risk Analysis Updated Clinical Evaluation Report
8	20 th November 2013	Update to address BSi TF audit observations and non-conformities September 2012
9	17 th December 2015	Update to letterhead to match market requirements
10	27 th February 2018	First issue in new Technical File format. Updated ERC checklist
11	05 th December 2018	Update to artwork (IFU and CTN) Revised JHT Protocol and Report Minor Update to CER
12	7 June 2021	Re-issued to align with Version 2 of WTTF-011
13	30 June 2022	Addition of Andersen Caledonia as supplier of steam sterilisation services