

EC Declaration of Conformity

Technical File WTTF-030 (PR/DL20-303)

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): AQUACEL® Foam Pro	
Product Codes	Applicable product codes are listed in the attached.	
Classification and Rule	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 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, hydrophilic-gel	
Harmonised Standards Applied:	EN ISO 13485: 2016 EN ISO 14971: 2012 EN ISO 10993-1: 2009 EN ISO 10993-3:2014 EN ISO 10993-5: 2009 EN ISO 10993-7: 2008	EN ISO 10993-11: 2009 EN ISO 10993-18: 2009 EN ISO 15223-1: 2016 EN 1041: 2008 EN ISO 11135-1: 2015 EN ISO 11607-1: 2009 EN ISO 13726-1: 2002

Issued in Deeside, UK.

Signed for and on behalf of ConvaTec Limited



Name: _____

Date: 26th November 2021

Gary Barrett

Vice President Regulatory Affairs

AQUACEL Foam Pro (PR/ DL 20-303)

Trade/ Brand Name: AQUACEL Foam Pro

Product Codes	Product Description
422356	AQUACEL® FOAM PRO HEEL19.8X14CM 1X10PK EU
422357	AQUACEL® FOAM PRO 10X10CM 1X10PK EU
422358	AQUACEL® FOAM PRO 15X15 1X10PK EU
422359	AQUACEL® FOAM PRO 8X8 1X10PK EU
421579	AQUACEL® FOAM PRO SACRAL STANDARD EUR
421580	AQUACEL® FOAM PRO SACRAL LARGE EUR
423520	AQUACEL® FOAM PRO HEEL19.8X14CM ES
423521	AQUACEL® FOAM PRO SACRAL 24.0X21.5CM ES
423522	AQUACEL® FOAM PRO 15X15 ES

History Page

Issue number	Date	Comment
1	30/AUG/2019	First Issue of DoC.
2	16/SEP/2019	Correction to Notified Body Address
3	27/SEP/2019	Removal of 421580 AQUACEL® FOAM PRO SACRAL LARGE EUR
4	13/NOV/2019	Inclusion of 421580 AQUACEL® FOAM PRO SACRAL LARGE EUR
5	31/JUL/2020	Update in line with Technical File WTTF-030 v. 4.0
6	16/Dec/2020	Updated DoC for addition of EC Representative
7	09/JUN/2021	Updated DoC due to add alternative primary packaging system supplied by Amcor
8	22/SEP/2021	Updated DoC to include Spanish packs (423520, 423521, 423522)
9	26/NOV/2021	Updated DoC in line with Technical File WTTF-030 v. 6.0