

## EC Declaration of Conformity

### Technical File CCCTF-011 {Fingertip Connectors DMR1040}

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): Fingertip Connectors - Sterile
Product Codes	Applicable product codes are listed in the attached.
Classification and Rule (Include Sterility / Measuring if applicable)	Class I (sterile), as defined by Rule 1, 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 <b>BSI Group The Netherlands B.V.</b> 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	CE 00364 MD 670405
GMDN Code and Term title	<b>10749-</b> Tracheal Suction Catheter
Harmonised Standards Applied:	ISO 13485: 2016 EN ISO 14971: 2012 EN ISO 10993-1: 2009 EN ISO 10993-5: 2009 EN ISO 10993-10: 2008 ISO 11135:2014 EN ISO 15223-1: 2016 EN 1041: 2008

Issued in Deeside, UK.

Signed for and on behalf of ConvaTec Limited

Name: *Diane Baker*

Date: 02-JAN-2020

Diane Baker Senior Director, Quality, Regulatory and Clinical, EMEA & CCC

Trade/Brand Name: Fingertip Connectors - Sterile

Product Codes	ICC Code	Product Description
84003181	505686	UNO FINGERTIP (100/ 1200) INT
84003182	505686	UNO FINGERTIP (100/1200) INT
84003183	505686	UNO FINGERTIP (100/1200) IT
84003184	505686	UNO FINGERTIP (100/1200) INT
84055022	505686	UNO FINGERTIP (100/1200) IT
84055023	417377	UNO FINGERTIP (100/ 1200) IT
86016571	504153	UNO FINGERTIP BULK (1/4000)
86016572	506033	Suction catheter /2 eyes/ fingertip CH14/ 51cm
86016573	504153	Suction catheter /2 eyes/ fingertip CH16/ 53cm

## Suction Catheter with Fingertip (1040/ PR60-115)

## History Page

Issue number	Date	Comment
1	20-Dec-2019	DOC updated into new format, for previous revisions of the Technical File and Declaration of Conformity linked to this specification please see DMR 1040.