

**EC Declaration of Conformity**  
**Technical File {WTSTF-006, PR/DL20-286}**


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 EXTRA
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) 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, 4320, Lejre, Denmark
EC Certification Number	00364
GMDN Code and Term title	43186 - Exudate-absorbent dressing, hydrophilic-gel
Harmonised Standards Applied:	EN ISO 13485:2016, EN ISO 10993:2009, EN ISO 14971:2012, EN1041:2008, EN 13726-1:2002, EN 13726-2:2002, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 11137-3:2009, ISO 15223-1:2016

Issued in Deeside, UK.

Signed for and on behalf of ConvaTec Limited

Name: 

Gary Barrett, Vice President, Regulatory Affairs

(06/May/2021)



{WTSTF-006, PR/DL20-286}

Trade/Brand Name: AQUACEL EXTRA

Product Codes	Product Description
420671	5 x 5 cm
420816	5 x 5 cm
420672	10 x 10 cm
420814	10 x 10 cm
420815	10 x 10 cm
420674	10 x 12 cm
420823	12.5 x 12.5 cm
422627	12.5 x 12.5 cm
420819	13.5 x 15 cm
422626	13.5 x 15 cm
420826	15 x 13.5 cm
420673	15 x 15 cm
420817	15 x 15 cm
420820	4 x 10 cm
420818	5 x 10 cm
420825	5 x 10 cm
420821	4 x 20 cm
420822	4 x 30 cm
420824	18 x 23 cm
422622	20 x 24 cm
423409	20 x 24 cm



# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.** CE 00364  
**Issued To:** **ConvaTec Limited**  
**First Avenue**  
**Deeside Industrial Park**  
**Deeside**  
**Flintshire**  
**CH5 2NU**  
**United Kingdom**

In respect of:

**The design, development and manufacture of sterile wound management dressings (incorporating alginate, hydrogel, foam, fibrous hydrocolloid, porcine gelatin based hydrocolloid and odour-absorbing technologies), sterile medicated wound dressings, sterile wound irrigation devices, sterile ostomy, non-sterile faecal incontinence systems; sterile catheters, cannulae and accessories (excluding intravascular, epidural and spinal); sterile suction sets, sterile gastroenterology tubing; sterile and non-sterile urinary drainage systems and accessories; sterile wound drainage systems, sterile surgical disposables; battery powered negative pressure wound therapy pumps and dressings.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **1994-12-09**

Date: **2021-03-15**

Expiry Date: **2023-10-20**

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This certificate was issued electronically and is bound by the conditions of the contract.

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Ames Goldsmith (U.K.) Limited Knowsley Industrial Park Kirkby Liverpool L33 7UF United Kingdom	<b>Crucial Supplier</b>
Aurena Laboratories AB Fjärrviksvägen 22 SE-653 50 Karlstad Sweden	<b>Manufacture</b>
Avery Dennison Belgie BV Tieblokkenlaan 1 B-2300 Turnhout Belgium	<b>Manufacture Packaging</b>

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Subcontractor:	Service(s) supplied
Baxter Healthcare Ltd Caxton Way Thetford Norfolk IP24 3SE United Kingdom	<b>Moist Heat Sterilization</b>
Brightwake Limited Lowmoor Business Park Kirkby in Ashfield Nottinghamshire NG17 7JZ United Kingdom	<b>Control of Sterilization</b> <b>Design</b> <b>Manufacture</b> <b>Packaging</b>
ConvaTec Dominican Republic, Inc Carretera Sanchez, Km. 18.5 Parque Industrial Itabo, S.A. Building 8A Haina, San Cristobal, 91000 Dominican Republic	<b>Control of Sterilization</b> <b>Manufacture</b> <b>Packaging</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
ConvaTec Dominican Republic, Inc. Carretera Sanchez, Km. 18.5 Parque Industrial Itabo, S.A. Building 23, 29, 30 Haina San Cristobal 91000 Dominican Republic	<b>Manufacture</b>
ConvaTec Inc. 7900 Triad Centre Drive Suite 400 Greensboro North Carolina 27409 USA	<b>Regulatory Compliance</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
ConvaTec Limited Global Development Centre First Avenue Deeside Industrial Park Deeside, Flintshire CH5 2NU United Kingdom	<b>Design Development</b>
ConvaTec Limited Units 1 & 2 Heads of the Valley Industrial Estate Rhymney, Tredegar NP22 5RL United Kingdom	<b>Manufacture</b>
ConvaTec Limited First Avenue Deeside Industrial Park Deeside, Flintshire CH5 2NU United Kingdom	<b>Manufacture</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Degania Silicone Limited Kibbutz 1513000 Degania Bet Israel	<b>Manufacture</b>
FE Unomedical Ltd Zavodskaya Str. 50 Fanipol 222750 Dzerzhinsk District Minsk Region Belarus	<b>Control of Sterilization</b> <b>Manufacture</b>
Fortune Medical Instrument Corp. No. 256, Changchun 2nd Rd., 320 Jhongli City Taoyuan County Taiwan	<b>Labelling</b> <b>Manufacture</b> <b>Packaging</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Fortune Medical Instrument Corp. 6F, No. 29, Sec. 2, Jhongjheng E. Rd. 251 Danshuei Dist. New Taipei City Taiwan	<b>Labelling</b> <b>Manufacture</b> <b>Packaging</b>
IntraPac (Mebane), Inc 1405 Dogwood Way Mebane North Carolina 27302 USA	<b>Labelling</b> <b>Manufacture</b> <b>Packaging</b>
Johnson Matthey Noble Metals Orchard Road Royston SG8 5HE United Kingdom	<b>Crucial Supplier</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
JSC Medplast Obyezdnaya str.12 Gomel Republic of Belarus 246051 Belarus	<b>ETO Sterilization</b>
Lake Chemicals & Minerals Limited, 3 Paper Mill Drive, Redditch B98 8QJ United Kingdom	<b>Crucial Supplier</b>
PB Leiner USA 7001 Brady Street Davenport Iowa 52806 USA	<b>Crucial Supplier</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
ReAgent 18 Aston Fields Road Whithouse Industrial Estate Runcorn Cheshire WA7 3DL United Kingdom	<b>Crucial Supplier</b>
Scandinavian Clinics Estonia OÜ Kurvi tee 406a Alliku küla Saue vald Harjumaa 76403 Estonia	<b>Radiation (Gamma Sterilization)</b>
Sterigenics Germany GmbH Kasteler Straße 45 Wiesbaden 65203 Germany	<b>ETO Sterilization</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Sterigenics UK Limited Cotes Park Lane Somercotes Alfreton DE55 4NJ United Kingdom	<b>ETO Sterilization</b>
Sterigenics UK Limited Seymour Link Road Woodthorpe, Mastin Moor Chesterfield S43 3FG United Kingdom	<b>Radiation (Gamma Sterilization)</b>
Sterigenics US, LLC 1148 Porter Avenue Haw River North Carolina 27258 USA	<b>Radiation (Gamma Sterilization)</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Sterigenics US, LLC 10811 Withers Cove Park Dr Charlotte North Carolina 28278 USA	<b>Radiation (Gamma Sterilization)</b>
Steris AST CS s.r.o Priemyselny park 6020/5 Michalovce 07101 Slovakia	<b>ETO Sterilization</b>
Synergy Health AST, Ede (Synergy Health PL, Ede) Morsestraat 3 6716 AH Ede The Netherlands	<b>Radiation (Gamma Sterilization)</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Synergy Health Ede BV Faunalaan 38, Venlo 5928 RZ The Netherlands	<b>ETO Sterilization</b>
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Reading) Marcus Close Tilehurst Reading RG30 4EA United Kingdom	<b>Radiation (Gamma Sterilization)</b>
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Bradford) Roydsdale Way Euroway Industrial Estate Bradford BD4 6SE United Kingdom	<b>Radiation (Gamma Sterilization)</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Daventry) Brunel Close Drayton Fields Industrial Estate Daventry NN11 8RB United Kingdom	<b>Radiation (Gamma Sterilization)</b>
Synergy Health Sterilisation UK Ltd (Synergy Health - AST - Swindon) Moray Road Elgin Industrial Estate Swindon SN2 8XS United Kingdom	<b>Radiation (Gamma Sterilization)</b>
Synergy Health Westport Ltd (Synergy Health - AST - Westport) Lodge Road Westport County Mayo Ireland	<b>Radiation (Gamma Sterilization)</b>

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<b>Subcontractor:</b>	<b>Service(s) supplied</b>
Unomedical A/S Aaholmvej 1-3, Osted 4320 Lejre Denmark	<b>EU Representative</b>
Unomedical s.r.o. Priemyselny Park 3 07101 Michalovce Slovakia	<b>Control of Sterilization Manufacture</b>

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# EC Certificate - Full Quality Assurance System

## Certificate History

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Date	Reference Number	Action
09 December 1994		First issue.
20 June 1995		Re-issued without change to content.
28 May 1996		Addition of sterilisation subcontractors.
09 October 1996		Addition of Tapemark Inc as an additional subcontractor.
04 November 1997		Re-issued without change to content.
22 April 1999		Addition of Ringers Solutions and CCL Pharmaceuticals as significant subcontractors.
10 December 1999		Minor changes to subcontractor address and responsibility details and the re-introduction of ConvaTec Greensboro following inadvertent omission from certificate.
18 February 2000		Addition of Baxter as an additional sterilisation subcontractor.
22 December 2000		Addition of ConvaTec Uxbridge as a subcontractor site for regulatory activities.

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Date	Reference Number	Action
22 April 2002		Addition of Avery Tape and Flexible Packaging as significant subcontractors and minor revisions to other subcontractor details.
21 October 2003		Addition of Aiolos Laboratories AB as a significant subcontractor. Name change of subcontractor Miza Pharmaceuticals to Inyx Pharma Ltd, and five year renewal.
16 February 2005		Addition of Tech Medical Plastics, Inc as a subcontractor and addition of "non-sterile before incontinence" in scope.
27 September 2005		Addition of 'manufacture' as an activity to ConvaTec GDC Site. Addition of Nypro Dominican Republic, Inc as a new subcontractor for manufacture.
11 June 2007		Removal of ConvaTec, S.L. and INyX Pharma Limited from the list of subcontractors. Change of name of subcontractor from Ion Beam Application to Sterigenics. Amendment to the name of subcontractor from Avery Speciality Tape Division Europe to Avery Dennison Belgie BV and change in service supplied from Manufacture to Sterile Manufacture.

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Date	Reference Number	Action
30 August 2007		Change of subcontractor's name from 'Nypro Dominican Republic, Inc' to 'ConvaTec Dominican Republic, Inc.' and amendment to their address.
29 October 2008	7214844	Certificate renewal. Minor corrections to subcontractor addresses, trading name of Aiolos Laboratories AB amended to Aurena Laboratories AB. Addition of subcontractor, Brightwake Limited, for design and manufacturing activities. Scope revised to give clarity to wound dressing technologies covered.
18 March 2009	7314713	Addition of sub-contractors Vesta Inc, Wisconsin and Fortune Medical Instrument Corp, Taiwan (2 sites) for activities related to the manufacture of Flexi-Seal devices.

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Date	Reference Number	Action
06 December 2010	7546472	Integration of new scope and subcontractors as a result of Unomedical A/S acquisition: Scope extended to include sterile catheters, cannulae and accessories (excluding intravascular, epidural and spinal); sterile suction sets, sterile tubing; sterile and non-sterile urinary drainage systems and accessories; sterile collection devices and accessories; sterile wound drainage systems, bags and accessories including systems for autotransfusion of filtered blood; sterile surgical disposables. New Subcontractors: FE Unomedical Ltd (Belarus) and Unomedical s.r.o. (Slovakia). Notified Body certificate ref relating to integrated activities: LNE #9536.
18 July 2011	7557034	Scope extension to include pneumatic compression system for wound management. New subcontractor: Scandinavian Health Ltd.

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Date	Reference Number	Action
31 May 2012	7816996	Addition of WEBTEC Converting, Knoxville for sterile manufacture, the change of name for significant subcontractor Isotron to Synergy Health Sterilisation UK.
19 July 2013	8023753	Addition of 'Control of Sterilization' to services supplied by significant subcontractor WEBTEC Converting LLC.
20 September 2013	8029244	Certificate renewal. Removal of significant subcontractors: Scandinavian Health Ltd, ConvaTec Limited Harrington House, Flexible Medical Packaging Limited. Addition of new significant subcontractor: Degania Silicone Limited. Removal of 'for wound management' in scope.

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Date	Reference Number	Action
24 May 2016	8374527 8430680	Administrative updates to certificate to amend addresses. Addition of new significant subcontractors Sterigenics UK Limited, Alfreton, UK. Addition of crucial suppliers: PB Leiner, Davenport, USA and Lake Chemicals & Minerals Limited, Redditch, UK (existing suppliers - first listing of crucial suppliers on certificate). Removal of the subcontractor: ConvaTec Inc., 200 Headquarters Park Drive, Skillman, New Jersey 08558, USA. Removal of the manufacturing activity at ConvaTec Limited, Global Development Centre, First Avenue, Deeside Industrial Park. Removal of "pneumatic compression systems" from the scope. Addition of "Battery powered negative pressure wound therapy pumps and dressings" to the scope expression. Plus the addition of packaging and control of sterilisation to the existing subcontractor Brightwake (design and manufacturing are already listed).



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Date	Reference Number	Action
30 June 2017	8768860	Subcontractor additions relating to NPWT devices: The Technology Partnership Plc, Plexus Corp., Harmac Medical Products and Synergy Health Westport Ltd., Sterilisation ETO subcontractor for Scapa Tapes North America: Sterilization Services Virginia (SSV), Sterilization Services Tennessee (SST), Sterilization Services Georgia (SSG).
16 March 2018	8886836	Removal of "including systems for autotransfusion of filtered blood" as this device is no longer being manufactured. Subcontractor minor address corrections. In addition ConvaTec Dominican Republic, Inc, Building 8A and activities are added; ConvaTec Inc, 7900 Triad Centre Drive has been added (Quality Assurance, Administration & Complaints). Convatec Inc, 211 American Avenue, Greensboro (manufacturing) has been deleted as the site has closed.

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Date	Reference Number	Action
23 October 2018	9653616	<p>The scope expressions "non-sterile faecal incontinence systems", "sterile gastroenterology tubing" have been added. No new devices added, but improved clarity from existing scope expressions.</p> <p>The scope expression "Sterile collection devices and accessories; bags and accessories" have been removed. No devices have been removed, but these overlap with existing scope expressions and are redundant.</p> <p>The subcontractors added are: Steris AST CS s.r.o., Michalovce, Slovakia; Synergy Health AST, Ede, The Netherlands; JSC MedPlast, Gomel, Belarus.</p>
07 March 2019	7779272	Traceable to NB 0086.

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Date	Reference Number	Action
17 July 2020	3203851	Addition of the Gamma Sterilisation subcontractors: Scandinavian Clinics Estonia OÜ, Estonia and Sterigenics UK Limited, Chesterfield. Addition of the ETO Sterilisation subcontractors: Synergy Health Ede BV, Venlo, The Netherlands and Sterigenics Germany GmbH, Wiesbaden Germany. Addition of an EU Representative: Unomedical A/S, Denmark. Removal of the subcontractors: Plexus Corp, Kelso, UK (Manufacturer); Harmac Medical Products, County Roscommon, Ireland (Packaging); TTP plc, Royston, UK (Design); Scapa Tapes North America LLC, Knoxville, USA (Manufacture / Control of Sterilisation); VESTA Inc, Wisconsin, USA (Labelling, Manufacturing, Packaging). Removal of the ETO Sterilisation subcontractors: Sterilisation Services of Georgia, Atlanta, USA; Sterilisation Services of Tennessee, Memphis, USA, Sterilisation Services of Virginia, Richmond, USA Name change from Technical Precision Plastics Inc to IntraPac (Mebane), Inc.
Current	3402556	Addition of crucial suppliers Ames Goldsmith (U.K.) Limited, Johnson Matthey Noble Metals, and ReAgent.

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