ConvaTec Limited
First Avenue
Deeside Industrial Park
Deeside
Flintshire
CH5 2NU
United Kingdom

04 July 2023

Notified Body Confirmation Letter

Reference: EU2023-607/651311

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

ConvaTec Limited
First Avenue
Deeside Industrial Park
Deeside
Flintshire
CH5 2NU
United Kingdom

SRN Number (if available): GB-MF-000001770

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Debbie Addison
Digitally signed by Debbie Addison
Date: 2023.07.04 11:46:29 +01'00'

Debbie Addison

BSI Scheme Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Aquacel Surgical Cover Dressing Basic UDI-DI: 768455AWC00203C	Class III	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797 MDD Certificate #2: CE 00380 Expiry date: 26/05/2024 NB#: 2797
Duoderm Extra Thin Basic UDI-DI: 768455AWC00303F	Class III	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797 MDD Certificate #2: CE 00380 Expiry date: 26/05/2024 NB#: 2797
Duoderm Signal Basic UDI-DI: 768455AWC00313H	Class III	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797 MDD Certificate #2: CE 00380 Expiry date: 26/05/2024 NB#: 2797
Duoderm CGF Basic UDI-DI: 768455AWC00323K	Class III	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797 MDD Certificate #2: CE 00380 Expiry date: 26/05/2024 NB#: 2797
Duoderm CGF Border Basic UDI-DI: 768455AWC00293W	Class III	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797 MDD Certificate #2: CE 00380 Expiry date: 26/05/2024 NB#: 2797
Aquacel Foam Basic UDI-DI: 768455AWC00063J	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Aquacel Foam Pro Basic UDI-DI: 768455AWC00073L	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797
Aquacel Extra & WSF Basic UDI-DI: 768455AWC00213E	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797
Carboflex Basic UDI-DI: 768455AWC00083N	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797
Duoderm Gel Basic UDI-DI: 768455AWC00093Q	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797
ConvaTec Foam Lite Basic UDI-DI: 768455AWC00193T	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797
Kaltostat Basic UDI-DI: 768455AWC00053G	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797
Avelle NPWT Dressing Basic UDI-DI: 768455AWC00033C	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797
Avelle NPWT Pump Basic UDI-DI: 768455AWC00023A	Class IIa	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797
Hydrocolloid Sealing Strips Basic UDI-DI: 768455AWC00163M	Class I device placed on the market in sterile condition	N/A	MDD Certificate #1: CE 56172 Expiry date: 20/10/2023 NB#: 2797
Loop Ostomy Rod Basic UDI-DI: 768455OST0005F5	Class IIa	N/A	MDD Certificate #1: CE 00364 Expiry date: 20/10/2023 NB#: 2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	Action
2023/07/04	Initial issue