Medeco B.V.
Brandpuntlaan Zuid 14
Bleiswijk
2665 NZ
The Netherlands

22nd April 2024

Notified Body Confirmation Letter

Reference: EU2023-607/836017

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:

Medeco B.V.
Brandpuntlaan Zuid 14
Bleiswijk
2665 NZ
The Netherlands

SRN Number: NL-MF-000001628

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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.,

Graeme Tunbridge
Senior Vice President, Medical Devices

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
Alginate Dressing Basic UDI-DI: 18756KLADM040402T6	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate: CE 607662 NB #: 2797
Foam Dressing Basic UDI-DI: 18756KLFDM040406WZ	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate: CE 607662 NB #: 2797
Silicone Foam Dressing Basic UDI-DI: 18756KLFDM040406WZ	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate: CE 607662 NB #: 2797
Hydrocolloid Dressing Basic UDI-DI: 18756KLHDM040403Y9	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate: CE 607662 NB #: 2797
Silicone Contact Layer Dressing Basic UDI-DI: 18756KLCLM040407ZN	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate: CE 607662 NB #: 2797
Superabsorbent Dressing Basic UDI-DI: 18756KLSAM0404997P	Class IIb excluding Class IIb implantable non-WET	N/A	MDD Certificate: CE 607662 NB #: 2797
Gauzes and Compresses Woven and Non-woven (JoJo) Basic UDI-DI: 18756KLNWM0202WC	Class IIa	N/A	MDD Certificate: CE 607662 NB #: 2797
X-ray Gauzes and Compresses Basic UDI-DI: 18756KLGXSM02010102013M	Class IIa	N/A	MDD Certificate: CE 607662 NB #: 2797
X-ray Gauzes and Compresses Basic UDI-DI: 18756KAGXM0201030201VV	Class IIa	N/A	MDD Certificate: CE 607662 NB #: 2797
X-ray Gauzes and Compresses (non-sterile) Basic UDI-DI: 18756KAGXM0201030201VV	Class IIa	N/A	MDD Certificate: CE 607662 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
X-ray Gauzes and Compresses Basic UDI-DI: 18756KLGSM0201057H	Class IIa	N/A	MDD Certificate: CE 607662 NB #: 2797
X-ray Gauzes and Compresses (non-sterile) Basic UDI-DI: 18756KLGXM020101029C	Class IIa	N/A	MDD Certificate: CE 607662 NB #: 2797
X-ray Gauzes and Compresses Basic UDI-DI: 18756KLNWXM020201JH	Class IIa	N/A	MDD Certificate: CE 607662 NB #: 2797
X-ray Gauzes and Compresses Basic UDI-DI: 18756KLNWXM020202JK	Class IIa	N/A	MDD Certificate: CE 607662 NB #: 2797
Ointment Dressing Basic UDI-DI: 18756KLODM0404996L	Class IIa	N/A	MDD Certificate: CE 607662 NB #: 2797
Bandages Basic UDI-DI: 18756KLADM040204SY	Class I device placed on the market in sterile condition	N/A	MDD Certificate: CE 607662 NB #: 2797
Gauzes and Compresses Woven and Non-woven (Exsupad/Novopad) Basic UDI-DI: 18756KLADM040204SY	Class I device placed on the market in sterile condition	N/A	MDD Certificate: CE 607662 NB #: 2797
Compresses/Alupad Basic UDI-DI: 18756KLADM040204SY	Class I device placed on the market in sterile condition	N/A	MDD Certificate: CE 607662 NB #: 2797
Sponges, Multipurpose Gauze Basic UDI-DI: 18756KLADM040204SY	Class I device placed on the market in sterile condition	N/A	MDD Certificate: CE 607662 NB #: 2797
Film dressing Basic UDI-DI: 18756KLFDM040406WZ	Class I device placed on the market in sterile condition	N/A	MDD Certificate: CE 607662 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
Gauzes and Compresses Woven and Non-woven (NW Compress) Basic UDI-DI: 18756KLPNWM0202F4	Class I device placed on the market in sterile condition	N/A	MDD Certificate: CE 607662 NB #: 2797
Sponges, Multipurpose Gauze (Comfort Compress) Basic UDI-DI: 18756KLPNWM0202F4	Class I device placed on the market in sterile condition	N/A	MDD Certificate: CE 607662 NB #: 2797
Gauzes and Compresses Woven and Non-woven (HG Compress) Basic UDI-DI: 18756KLHGM0201LL	Class I device placed on the market in sterile condition	N/A	MDD Certificate: CE 607662 NB #: 2797
Plasters Basic UDI-DI: 18756KLPLM040101A9	Class I device placed on the market in sterile condition	N/A	MDD Certificate: CE 607662 NB #: 2797
Film IV Dressing Basic UDI-DI: 18756KLPLM040101A9	Class I device placed on the market in sterile condition	N/A	MDD Certificate: CE 607662 NB #: 2797
Film IV Dressing (non-woven) Basic UDI-DI: 18756KLFLM0401MV	Class I device placed on the market in sterile condition	N/A	MDD Certificate: CE 607662 NB #: 2797
Syringes Basic UDI-DI: 18756CEA020108MA	Class I device placed on the market in sterile condition	N/A	MDD Certificate: CE 607662 NB #: 2797
Urine Collection Bags Basic UDI-DI: 18756CUA060303Y6	Class I device placed on the market in sterile condition	N/A	MDD Certificate: CE 607662 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	Choose an item.	N/A	N/A

Confirmation Letter Revision History

Date	Action
2024/04/22	Initial issue