MEDIANA Co., Ltd.
132, Donghwagongdan-ro
Munmak-eup
Wonju-si
Gangwon-do
26365
Republic of Korea

2023-09-13

Notified Body Confirmation Letter

Reference: EU2023-607/687760

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:

MEDIANA Co., Ltd.
132, Donghwagongdan-ro
Munmak-eup
Wonju-si
Gangwon-do
26365
Republic of Korea

KR-MF-000026570

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

Takato Akimoto

Digitally signed by Takato Akimoto
Date: 2023.09.13 10:30:30 +09'00'

Takato Akimoto

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
A16, 88000034HeartOnA16NS	Class III	Not Applicable	CE 691292, 2023-11-05, 2797
A15, 88000034HeartOnA15NQ	Class III	Not Applicable	CE 691292, 2023-11-05, 2797
D700, 88000034D700B7	Class III	Not Applicable	CE 691292, 2023-11-05, 2797
V10 88000034V10RZ	Class IIb excluding Class IIb implantable non-WET	Not Applicable	CE 691292, 2023-11-05, 2797
M32, 88000034M32QW	Class IIb excluding Class IIb implantable non-WET	Not Applicable	CE 691292, 2023-11-05, 2797
V20a 88000034V20S4	Class IIb excluding Class IIb implantable non-WET	Not Applicable	CE 691292, 2023-11-05, 2797
M50, 88000034M50QY	Class IIb excluding Class IIb implantable non-WET	Not Applicable	CE 691292, 2023-11-05, 2797
M40, 88000034M40QV	Class IIb excluding Class IIb implantable non-WET	Not Applicable	CE 691292, 2023-11-05, 2797
InfoWareG, 88000034INFOWAREGAX	Class IIb excluding Class IIb implantable non-WET	Not Applicable	CE 691292, 2023-11-05, 2797
I20/I25, I30/I35, 88000034BCARG	Class IIa	Not Applicable	CE 691292, 2023-11-05, 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
Not Applicable			

Confirmation Letter Revision History

Date	Action
2023/09/13	Initial issue