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

2024-04-02

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:

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

[redacted]

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
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
D500 88000034D500AV	Class III	Not Applicable	CE 691292, 2023-11-05, 2797
M20 88000034M20QP	Class IIb excluding Class IIb implantable non-WET	Not Applicable	CE 691292, 2023-11-05, 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
M30 88000034M30QS	Class IIb excluding Class IIb implantable non-WET	Not Applicable	CE 691292, 2023-11-05, 2797
D100 88000034D100A9	Class III	Not Applicable	CE 691292, 2023-11-05, 2797
I50/I55 88000034BCA506K	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
2024/02/28	Immediate re-application D700, V10, M32, V20a, M50, M40, InfoWareG, I20/I25, I30/I35 after refusal of application of above devices. Addition of D500, M20, M30, D100, and I50/I55 in the list of the confirmation letter.
2024/04/02	Change of Signature

By Royal Charter

EC Certificate - Full Quality Assurance System

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

No. **CE 691292**

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

In respect of:

The design and manufacture of defibrillators, Patient Monitors, Central Monitoring System, Electrocardiograph (ECG), and Body Composition Analyzer.

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: **2018-05-22** Date: **2020-03-23** Expiry Date: **2023-11-05**

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EC Certificate - Full Quality Assurance System

Supplementary Information to CE 691292

Issued To:

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Class IIb		
GMDN	Device or Generic Device Group	Intended purpose as per IFU
33586	Patient monitor	The monitor is intended to be used to monitor Electrocardiography (ECG), Heart rate (HR), Non-invasive blood pressure (NIBP) - systolic, diastolic and mean arterial pressures, functional arterial oxygen saturation (SpO2), Pulse rate (PR), Respiration rate (RR), Temperature (Temp), Capnography (EtCO2 and InCO2), Invasive blood pressure (IBP), Bispectral Index (BIS) and/or Multi gas and for adult, pediatric and neonatal patients in all areas of a hospital and hospital-type facilities. Monitor users should be skilled at the level of a technician, doctor, nurse or medical specialist. The vital sign monitor is only suitable for single measurement.
36870	Central Monitoring System	The intended use of the CMS is to display physiologic waves, parameters, and trends, format data for strip chart recordings and printings, and provide the annunciation of alarms from other networked Patient Monitor or Defibrillators/Monitors at a centralized location. The CMS provides for the retrospective review of alarms, physiologic waves and parameters from its database. The CMS is used in all areas of a hospital and hospital-type facilities and it is not intended to use at home environments. Users should be skilled at the level of a technician, doctor, nurse or medical specialist.

First Issued: **2018-05-22** Date: **2020-03-23** Expiry Date: **2023-11-05**

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47910	Automated External Defibrillator	The AED is intended to be used to treat someone who is unresponsive, non-breathing and pulseless for the adult and pediatric in all area of a hospital, pre-hospital, public access, alternate care and home healthcare environment. AED is designed to easy to use.
17882	Defibrillator/Monitor	The defibrillator/monitor is intended for use by trained medical technician, doctor, nurse or medical specialist in outdoor and indoor emergency care settings including air and ground ambulances within the environmental conditions specified. Manual and Automated external defibrillation, External pacing, Diagnostic electrocardiography (12-lead ECG) are intended for use on adult and pediatric patients. The other monitoring functions, Electrocardiography (ECG), Heart Rate(HR), Non-invasive blood pressure (NIBP), Functional arterial oxygen saturation (SpO2), Respiration (RESP), Temperature (TEMP) and/or Invasive blood pressure (IBP) are intended for use on adult, pediatric and neonatal patients. End tidal CO2 (EtCO2) are intended for use on adult, pediatric and infant patients.
Class IIa		
NBOG code	Device or Device subcategory	----
MD1302	Electrocardiograph (ECG)	----
MD1301	Body Composition Analyzer	----

First Issued: **2018-05-22** Date: **2020-03-23** Expiry Date: **2023-11-05**

By Royal Charter

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:

Certificate No:	**CE 691292**
Date:	**2020-03-23**
Issued To:	**MEDIANA Co., Ltd.** **132, Donghwagongdan-ro** **Munmak-eup** **Wonju-si** **Gangwon-do** **26365** **Republic of Korea**

Subcontractor:	**Service(s) supplied**
Obelis s.a Bd. Général Wahis 53 1030 Brussels Belgium	**EU Representative**

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 691292**

Date: **2020-03-23**

Issued To: **MEDIANA Co., Ltd.**
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Date	Reference Number	Action
22 May 2018	8918854	First Issue. Transfer from another Notified Body.
05 November 2018	9664401	Certificate Renewal.
26 February 2019	8942092	Traceable to NB 0086.
Current	3083607	Certificate re-issue due to addition of Body Composition Analyzer in the scope of the certificate. Deletion of EU representative page as now only single EU representative is used. Addition of product list. Deletion of Medigate Inc from significant subcontractor list.