

**Notified Body Confirmation Letter**

2024-05-23

MESI, razvoj medicinskih naprav, d.o.o.

Leskoškova cesta 11A

1000 Ljubljana

Slovenija

Notified Body Confirmation Letter**Reference: 4581-2024/01**

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 as regards the transitional provisions for certain medical devices.

This letter confirms that, SIQ Ljubljana, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1304 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:

Company Name	MESI, development of medical devices, Ltd.,
Legal address/street	Leskoškova c.11a
Zip code/town	1000 Ljubljana
Country:	Slovenia
SRN number	SI-MF-000007761

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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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

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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 the Notified Body,


 Ana Pribaković Borštnik
 Product manager MDR



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 DEVICE	MDD CERTIFICATE REFERENCE(S) OF THE DEVICES UNDER MDR APPLICATION, AND THE NB IDENTIFICATION
Automated ankle brachial pressure index measuring device ABPIMD 383005985ABPIMDDEL	Class IIa	N/A	MDD-037, NB1304
MESI mTABLET ABI diagnostic system MTABSYSABI 383005985MTABSYSABIJY	Class IIa	N/A	MDD-081, NB1304

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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 DEVICE	MDD CERTIFICATE REFERENCE(S) OF THE DEVICES UNDER MDR APPLICATION, AND THE NB IDENTIFICATION
MESI mTABLET BP diagnostic system MTABSYSBP 383005985MTABSYSB PSM	Class IIa	N/A	MDD-081, NB1304
MESI mTABLET TBI diagnostic system 383005985MTABSYST BIMX MTABSYSTBI	Class IIa	N/A	MDD-081, NB1304
MESI mTABLET SPO2 diagnostic system 383005985MTABSYS PO2M7 MTABSYSPO2	Class IIa	N/A	MDD-081, NB1304
MESI mTABLET ECG diagnostic system MTABSYSCEG 383005985MTABSYS CGKK	Class IIa	N/A	MDD-081, NB1304

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 DEVICE	MDD 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	NB INTERNAL REFERENCE TRACEABLE TO EACH VERSION OF THE LETTER	ACTION
2024-05-23	4581-2024/ 01	Initial issue