

TÜV Rheinland LGA Products GmbH • 51105 Köln

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20-701 Lublin
Poland

Contact

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Date February 22, 2024

Notified Body Confirmation Letter

Reference. : 60427/2024

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 **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** 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:

M4Medical Sp. z o.o.
ul. Nałęczowska 14
20-701 Lublin
Poland
PL-MF-000022164

The devices covered by the formal application and the written agreement mentioned above are identified in the table 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 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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 March 20, 2023 for the relevant devices.

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Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübi

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:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 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)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 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

Certification body

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
M-TRACE ECG 6 View Plus ECG EOLYS CARDIOCOR MIDAS 6/12 MIDAS 6/12 I	Class IIa	M-TRACE ECG 6 View Plus ECG EOLYS CARDIOCOR MIDAS 6/12 MIDAS 6/12 I	HD1497993-1 #0197
M-TRACE mini MIDAS 6/12 mini EOLYS mini	Class IIa	M-TRACE mini MIDAS 6/12 mini EOLYS mini	HD1497993-1 #0197
M-TRACE PC ECG PC EOLYS PG ECG	Class IIa	M-TRACE PC ECG PC EOLYS PG ECG	HD1497993-1 #0197
M-TRACE mobile	Class IIa	M-TRACE mobile	HD1497993-1 #0197
M-TRACE PC BASE	Class IIa	M-TRACE PC BASE	HD1497993-1 #0197

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/02/22	Rev.1	Initial issue