DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

Labtech Kft

Vág u. 4
4031 Debrecen
Hungary

Date: 24th October 2024

Notified Body Confirmation Letter
Reference: 1000179490

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, DQS Medizinprodukte GmbH, a Notified Body designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 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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SRN: HU-MF-000002846

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables listed below: Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which DQS Medizinprodukte GmbH 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 DQS Medizinprodukte GmbH 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that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 the Notified Body,

Andreas Dreimann
Senior Regulatory Affairs 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 and Basic UDI-DI (as proposed by the manufacturer within the 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
EC type resting and stress test ECG systems **(V6 version)** 5999883490ECGSRY Types: EC-12R V6 (V6 version) EC-12S V6 (V6 version) EC-12R/S V6 (V6 version) EC-12RM V6 (V6 version) EC-3S V6 (V6 version) EC-3R/S V6 (V6 version) EC-3REHAB V6 (V6 version)	Class IIa	EC type resting and stress test ECG systems (Types: EC-12R (V5 version) EC-12S (V5 version) EC-12R/S (V5 version) EC-12RM (V5 version) EC-12LT (OEM-OBL treadmill manufactured by LODE B.V.)	For device versions listed in the previous column: Certificate nr. 5-850-200-1806 (neoEMKI 1011) The new versions listed in the first column and which differ from the devices listed in the previous column there was no MDD certification. EC-12LT device will not be certified according to MDR
EC type Holter systems 5999883490HOLTERSR9 Types: EC-2H (V6 version) EC-3H (V6 version) EC-12H (V6 version) EC-ABP V6 (V6 version) EC-3H/ABP V6 (V6 version) EC-12H/ABP V6 (V6 version)	Class IIa	EC type Holter systems (Types: EC-2H (V6 version) EC-3H (V6 version) EC-12H (V6 version) EC-ABP (V5 version) EC-3H/ABP (V5 version)	For device versions listed in the previous column: Certificate nr. 5-850-200-1806 5-850-200-1806 (neoEMKI 1011) The new versions listed in the first column and which differ from the devices listed in the previous column there was no MDD certification.

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
24th October 2024	1000179490	Initial issue