



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

**Radimed Gesellschaft  
für Kommunikationsdienstleistungen und Medizintechnik mbH**

Lothringer Straße 36b  
44805 Bochum  
Germany

Date: 2024-03-18

**Notified Body Confirmation Letter  
Reference: 1000167735**

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:

**Radimed Gesellschaft für Kommunikationsdienstleistungen und  
Medizintechnik mbH**

Lothringer Straße 36b  
44805 Bochum  
Germany

SRN: DE-MF-000006540

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that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

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- 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,

A handwritten signature in black ink, appearing to read 'N. Wimmer'.

**Natalie Wimmer**

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:**

<b>Device name and Basic UDI-DI (as proposed by the manufacturer within the application)</b>	<b>MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)</b>	<b>If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device</b>	<b>MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification</b>
<b>Fine needles</b> Cannulae, Other 15-206 426014668KANUELE018E	Class IIa	N/A	44 235 200407 NB 0044
<b>Thermolesion cannulas</b> Electrosurgical Unit Adapters, Hand Control 11-494 426014668THERMO01XA	Class IIa	N/A	44 235 200407 NB 0044
<b>Thermoelectrodes Single use</b> Electrodes, Other 15-217 426014668THERMO02XC	Class IIa	N/A	44 235 200407 NB 0044
<b>Thermoelectrodes reusable</b> Electrodes, Other 15-217 426014668THERMO03XE	Class IIa	N/A	44 235 200407 NB 0044
<b>Laser fibers single use</b> Laser delivery systems, Fiberoptic 17-807 426014668LASER01CR	Class IIa	N/A	44 235 200407 NB 0044
<b>Laserfiber Fixing Device</b> Fittings/Adapter, Luer 11-729 426014668LASER03CV	Class I devices placed on the market in sterile condition (not verified yet)	<b>Fiberoptic Fixing Device</b> Fittings/Adapter, Luer 11-729	44 235 200407 NB 0044

**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:**

<b>Device name and Basic UDI-DI (as proposed by the manufacturer within the application)</b>	<b>MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)</b>	<b>If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device</b>	<b>MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification</b>
N/A	N/A	N/A	N/A

**Confirmation Letter Revision History**

<b>Date</b>	<b>NB internal reference traceable to each version of the letter</b>	<b>Action</b>
2024-03-18	1000167735	Initial issue
	Cert-ID	description of change (e.g. addition of device XYZ to Table 1)
	Cert-ID	description of change (e.g. removal of device XYZ from Table 2)