Manufacturer's Declaration

in relation to 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, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Radimed GmbH
Manufacturer address and contact details	Lothringer Str. 36b 44805 Bochum Germany Ralf Klein – klein@radimed.de
Single Registration Number (SRN) (if available)	DE-MF-000006540

Notified body name (if applicable)	TÜV Nord cert □ See attached schedule
Notified body number (if applicable)	0044 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	44 235 200407 □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2024-05-26 □ See attached schedule
End date of extended validity/transition period	2028-31-12 □ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **devices** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate** as listed above or in the attached schedule

- Directive Certificate covering the listed devices) was valid on 26 May 2021 and has not been withdrawn afterwards.
- Expired/expires *after* 20 March 2023.
- Formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made to the notified body DQS Medizinprodukte GmbH (0297), for the devices listed in the attached schedule or its/their substitute(s). The written agreement was signed in accordance with Section 4.3, second subparagraph of Annex VII MDR at 20 Oct 2023.

➢ **Quality Management System (QMS)**

- A QMS in accordance with Article 10(9) MDR is in place and was successfully audited by DQS med in Oct 2023.

➢ **Devices as listed in the attached schedule**

- The devices continue to comply with the MDD.
- There are no significant changes in the design and intended purpose according to MDCG 2020-03.
- The devices do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Radimed GmbH, Lothringer Str. 36b, 44805 Bochum, Germany

Bochum, Jan, 1st. 2024 /	Jan Henke *-General manager -*	Ralf Klein *-General manager -*

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Fine needles *Cannulae, other 15-206*	44 235 200407	26.05.2024	TÜV Nord cert 0044	DQS med 0297	31.12.2028	No
Thermolesion cannulas *Electrosurgical Unit Adapters 11-494*	44 235 200407	26.05.2024	TÜV Nord cert 0044	DQS med 0297	31.12.2028	No
Thermoelectrodes Single use *Electrodes, other 15-217*	44 235 200407	26.05.2024	TÜV Nord cert 0044	DQS med 0297	31.12.2028	No
Thermoelectrodes reusable *Electrodes, other 15-217*	44 235 200407	26.05.2024	TÜV Nord cert 0044	DQS med 0297	31.12.2028	No
Laser fibers single use *Laser delivery systems, Fiberoptic 17-807*	44 235 200407	26.05.2024	TÜV Nord cert 0044	DQS med 0297	31.12.2028	No
Fiberoptic Fixing Device *Fittings/Adapter, Luer 11-729*	44 235 200407	26.05.2024	TÜV Nord cert 0044	DQS med 0297	31.12.2028	Yes

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)