TÜV Rheinland Italia S.r.l.
Sicurezza e Qualità Prodotto

TÜV Rheinland Italia S.r.l.
Via Mattei 3
20005 Pogliano Milanese (MI)
Italia

Via del Faggiolo 1/12
40132 Bologna
Italia

EME S.r.l.
Registered and Operational Headquarter:
Via degli Abeti, 88/1
61122 Pesaro (PU)

Alla c.a.
Dott. Pieraccini Alessandro

Date: 24/05/2024

Object: 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

Dear Dott. Pieraccini

This letter confirms that, TUV RHEINLAND ITALIA, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1936 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:

EME S.r.l.
Registered and Operational Headquarter:
Via degli Abeti, 88/1
61122 Pesaro (PU)

Digitally signed by Jighili Tatiana
Date: 2024.06.10 11:14:12 EEST
Reason: MoldSign Signature
Location: Moldova

The devices covered by the formal application and the written agreement mentioned above are identified in the Table below
The table identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB

- has <u>not</u> yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive showed on Certificate no° MED 31009
- has taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive showed on Certificate no° HD 60139851

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Sede Legale ed operativa
Membro del Gruppo
TÜV Rheinland

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Capitale sociale
EURO 51.000,00 int. versato
C.C.I.A.A. Milano No. 1535451
Registro Milano No. 214918
CF e IVA 12184570153

In the case of devices covered by certificates issued or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry.

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)

Devices covered by this letter, and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive, and identified on the basis of the indications provided in the MDR application received:

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer)**	**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**
Radarmed 2500 CP **Microradar puls** **Combimed 4000** **Polyter Evo** **KOMBY EXCELLENT** **Lasermed 2200** **Medilaser** **PR999 4W** **PR999 8W**	Class IIb	N/A	Certificate issued by Kiwa Cermet Italia S.p.A. Certificate no: MED 31009 Annex II except point 4 Date of issue 01/02/2011 Date of expiry 26/05/2024

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Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer)	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
Electromed 2 LMF **Therapic 9200** **Therapic 9400** **Medison 1/3** **Ultrasonic 1300** **Ultrasonic 1500** **Combimed 2200** **Medicomb**			
Magnetomed 7200 **Magnetomed 8400** **MEDI MAG 2** **Magneto 2** **Magneto 4** **Mag Expert**	Class IIa	N/A	Certificate issued by Kiwa Cermet Italia S.p.A. Certificate no: MED 31009 Annex II except point 4 Date of issue 01/02/2011 Date of expiry 26/05/2024
Devices covered by this letter, and for which the NB is responsible for appropriate surveillance of the corresponding devices under the applicable Directive, and identified on the basis of the indications provided in the MDR application received:			
Mo-Vit TLM **Ref.code: MV001**	Class IIa	N/A	Certificate issued by TÜV RHEINLAND ITALIA Certificate no: HD 60139851 Annex II except point 4 Date of issue 09/07/2019 Date of expiry 26/05/2024
SHOCK MED **Ref.code: SW2050** **SHOCK MED SP** **Ref.code: SW2051** **HR TEK** **Ref.code: HT2043** **HR TEK SP** **Ref.code: HT2044** **CRYSTAL YAG**	Class IIb	N/A	Certificate issued by TÜV RHEINLAND ITALIA Certificate no: HD 60139851 Annex II except point 4 Date of issue 09/07/2019 Date of expiry 26/05/2024

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Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer)	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
Ref.code: HL2063 **CRYSTAL YAG SP** **Ref.code: HL2065** **BIPOWER LUX** **Ref.code. HL2062** **BIPOWER LUX SP** **Ref.code: HL2064**			

TUV RHEINLAND ITALIA (n.1936)

Andrea Franceschini
Project Manager

Annex: Certificate No. HD 60139851 issued by TÜV RHEINLAND ITALIA
Annex: Certificate No. MED 31009 issued by Kiwa Cermet Italia S.p.A.

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