

#### 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

Date: 24/05/2024

EME S.r.I.

Registered and Operational
Headquarter:
Via degli Abeti, 88/1
61122 Pesaro (PU)

Alla c.a. **Dott. Pieraccini Alessandro** 

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.I. Registered and Operational Headquarter: Via degli Abeti, 88/1 61122 Pesaro (PU)

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

TÜV Rheinland Italia S.r.I. Sede Legale ed operativa Membro del Gruppo TÜV Rheinland

Via Mattei, 3 20005 Pogliano Milanese (MI)

Tel: +39.02.939.687.1 Fax: +39.02.939.687.23 E-mail:informazioni@it.tuv.com Web:www.tuvitalia.com



### TÜV Rheinland Italia S.r.I. Sicurezza e Qualità Prodotto

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issued or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry.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	Class IIb	N/A	Certificate issued by
Microradar puls			Kiwa Cermet Italia S.p.A.
			Certificate no: MED 31009
Combimed 4000			Annex II except point 4
Polyter Evo			Date of issue 01/02/2011
KOMBY EXCELLENT			Date of expiry 26/05/2024
Lasermed 2200			
Medilaser			
PR999 4W			
PR999 8W			

TÜV Rheinland Italia S.r.I. Sede Legale ed operativa Membro del Gruppo TÜV Rheinland

Via Mattei, 3 20005 Pogliano Milanese (MI)

Tel: +39.02.939.687.1 Fax: +39.02.939.687.23 E-mail:informazioni@it.tuv.com Web:www.tuvitalia.com



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

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	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
CRYSTAL YAG			

TÜV Rheinland Italia S.r.I. Sede Legale ed operativa Membro del Gruppo TÜV Rheinland

Via Mattei, 3 20005 Pogliano Milanese (MI)

Tel: +39.02.939.687.1 Fax: +39.02.939.687.23 E-mail:informazioni@it.tuv.com Web:www.tuvitalia.com



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

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.

TÜV Rheinland Italia S.r.l. Sede Legale ed operativa Membro del Gruppo TÜV Rheinland

Via Mattei, 3 20005 Pogliano Milanese (MI)

Tel: +39.02.939.687.1 Fax: +39.02.939.687.23 E-mail:informazioni@it.tuv.com Web:www.tuvitalia.com