CERTIFICATE

Digitally signed by Iurchevici Valeriu
Date: 2024.11.08 15:40:25 EET
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

The Certification Body TÜV Rheinland Italia S.r.l.

certifies, in accordance with the TÜV Rheinland Group procedures, that the Company

EME S.r.l.

Via degli Abeti, 88/1

61122 Pesaro (PU) – Italy

has established and applies a quality management system
for the following scope:

Design, manufacture and placing on the market of electromedical equipment for physiotherapy, rehabilitation and aesthetic medicine.

Through an Audit, Report No. 7991503010AF12, proof has been furnished that the quality management system fulfils the requirements of the standard

UNI CEI EN ISO 13485:2021

Please refer to the Quality Manual for the details about
the exclusions with respect to the requirements of the standard.

Certificate Registration No. **39 05 1232408**

This Certificate is valid from 2024/09/13 to 2024/12/27

The reference date for all the next audits is (day-month): 27/12

Milan, 2024/09/13. First Certification: 2011/02/01

The certification responsible: Daniele Ricchi
TÜV Rheinland Italia S.r.l., Via E. Mattei, 3 - I - 20005 Pogliano Milanese (MI)

This certificate does not represent proof that the statutory requirements of the Directives 93/42/EEC, 90/385/EEC, 98/79/EC or Regulations (UE) 2017/745, (UE) 2017/746 have been fulfilled

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
MS N° 0083
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC.
Signatory of EA, IAF and ILAC Mutual Recognition Agreements.

TÜVRheinland CERTIFIED
Management System
EN ISO 13485:2016
www.tuv.com
ID 9000034494

www.tuvitalia.com

TÜVRheinland®

CERTIFICATE

Reg. Number	8998 - A	Valid From	2021-12-23
First issue date	2011-02-01	Last change date	2021-12-23
Valid Until	2024-12-27	IAF Sector	19

Quality Management System Certificate

ISO 9001:2015

We certify that the Quality Management System of the Organization:

EME S.r.l.

Is in compliance with the standard UNI EN ISO 9001:2015 for the following products/services:

Design, manufacturing of electromedical equipment for physiotherapy, rehabilitation and medical aesthetic sectors. Design, manufacturing of electronic equipment for aesthetic sectors.

Chief Operating Officer
Giampiero Belcredi

The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.

This certificate is composed of 1 page.

Kiwa Cermet Italia S.p.A.
Società con socio unico, soggetta all'attività di direzione e coordinamento di Kiwa Italia Holding Srl
Via Cadriano, 23
40057 Granarolo dell'Emilia (BO)
Tel +39.051.459.3.111
Fax +39.051.763.382
E-mail: info@kiwacermet.it
www.kiwa.it

EME S.r.l.
Registered Headquarters
- Via degli Abeti, 88/1 61122 Pesaro Italia

Certified Sites
- Via degli Abeti, 88/1 61122 Pesaro Italia

DICHIARAZIONE DI CONFORMITÀ ALLA DIRETTIVA 93/42/CEE SUI DISPOSITIVI MEDICI

EME ITALY
Aesthetic & Medical Technologies

DECLARATION OF CONFORMITY TO THE 93/42/CEE DIRECTIVE ON MEDICAL DEVICES

Il Fabbricante / *The manufacturer*

EME Srl - Via degli Abeti , 88 / 1 - 61122 PESARO (PU) - ITALY

dichiara sulla sua responsabilità che il prodotto :
declares on its own responsibility that the product :

Apparecchiature per terapia ad onde d'urto /
Equipment for shock-wave therapy:

SHOCK MED

è conforme ai requisiti essenziali della direttiva comunitaria 93/42/CEE e successive integrazioni e modifiche (Allegato I), recepita in Italia con
D.L. N° 46 del 24 febbraio 1997 e successive integrazioni e modifiche,
e la classe di rischio è la IIb secondo la regola 9.

is in compliance with the essential requirements of 93/42/CEE Directive and the following integrations and modifications (Annex I) , implemented in Italy following the D.L. N° 46 directive issued on 24 february 1997, and the risk class is IIb *according to the rule 9.*

Certificato n. HD 60139851 / *Certificate n. HD 60139851*

Allegato II escluso punto 4 / *Annex II except point 4*

La macchina è marcata / *The equipment is marked*:

CE 1936

Organismo Notificato / *Notified Body*
TÜV Rheinland Italia S.r.l.

Pesaro, 28/04/2020

EME srl
L'Amministratore unico / Administrator
Salvatore Vanella

DICHIARAZIONE DI CONFORMITÀ ALLA DIRETTIVA 93/42/CEE SUI DISPOSITIVI MEDICI

EME ITALY
Aesthetic & Medical Technologies

DECLARATION OF CONFORMITY TO THE 93/42/CEE DIRECTIVE ON MEDICAL DEVICES

Il Fabbricante / *The manufacturer*

EME Srl - Via degli Abeti , 88 / 1 - 61122 PESARO (PU) - ITALY

dichiara sulla sua responsabilità che il prodotto :
declares on its own responsibility that the product :

Apparecchiature per ultrasuono terapia /
Equipment for ultrasounds therapy :

ULTRASONIC 1300 - ULTRASONIC 1500

è conforme alle prescrizioni della direttiva comunitaria 93/42/CEE e successive integrazioni e modifiche (Allegato II eccetto il punto 4), recepita in Italia con D.L. N° 46 del 24 febbraio 1997 e successive integrazioni e modifiche , e la classe di rischio è la IIb secondo la regola 9.

is in compliance with the 93/42/CEE Directive and the following integrations and modifications (Annex II except point 4) , implemented in Italy following the D.L. N° 46 directive issued on 24 february 1997, and the risk class is IIb *according to the rule 9.*

Certificato n. MED – 31009 / *Certificate n. MED – 31009*

La macchina è marcata / *The equipment is marked* :

CE 0476

Organismo Notificato / *Notified Body*
Kiwa Cermet Italia S.p.a.

Pesaro, 14/04/2016

EME srl
L'Amministratore unico / Administrator