Certificato di conformità CE

EC Certificate of Conformity

TÜVRheinland®

Sistema completo di garanzia di qualità secondo direttiva 93/42/CEE allegato II escluso punto 4

EC Directive 93/42/EEC Annex II, excluded clause 4 Full Quality Assurance System Medical Devices

Certificato n°: **HD 60149156**

Registration No:

Fabbricante: **Wavemed S.r.l.**

Manufacturer:

Sede legale: **Via della Comunicazione, 4**

Registered Headquarter: **00030 – San Cesareo (RM)**

Sede operativa: **Via della Comunicazione, 4**

Operational Headquarter: **00030 – San Cesareo (RM)**

Scopo: **Dispositivi per stimolazione o inibizione/** *Devices for stimulation or inhibition*

Scope:

(Vedere allegato tecnico al presente Certificato per tipologie, modelli e codici)
(*See the attachment for typologies, models and codes designation)*

L'organismo notificato dichiara che il Sistema di qualità stabilito ed applicato dalla società sopra specificata soddisfa i requisiti dell'allegato II, articolo 3 della suddetta direttiva. Questa approvazione è soggetta a sorveglianza periodica, così come definita nell'allegato II, articolo 5 della suddetta direttiva e può essere utilizzata congiuntamente alla dichiarazione di conformità redatta dal fabbricante. / The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5, of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

L'organismo notificato/ ***Notified Body***

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

Paolo Caglio

Data di emissione/*Issue date*: **10/06/2020**

Data di ultima modifica/*Last revision date:* **20/05/2021**

Data di scadenza/*Expiry date:* **26/05/2024**

TÜV Rheinland Italia S.r.l. - Via Mattei, 3 - 20010 - Pogliano Milanese (MI)

Autorizzata dal Ministero della Salute e dal Ministero dello Sviluppo Economico

Accredited by Ministry of Health and by Ministry of Economic Development

Organismo notificato con il numero 1936 presso la Commissione Europea

Notified under No. 1936 to the EC Commission

CE La marcatura CE può essere apposta esclusivamente se vengono soddisfatti I requisiti di tutte le direttive CE applicabili CE

The CE marking may be used if all relevant and effective EC Directives are complied with

10/020 h 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

Allegato tecnico al Certificato n° HD 60149156

Attachment to the certificate:

Fabbricante/*Manufacturer:* **Wavemed S.r.l.**

Scopo/*Scope:* **Dispositivi per stimolazione o inibizione/** *Devices for stimulation or inhibition*

Tipologia/ *Typology:* **Dispositivo modulare a radiofrequenza, ultrasuoni, diatermia, luce pulsata, carbossiterapia, elettroporazione e laser per applicazioni medicali/** *Radiofrequency, ultrasound, diathermy, intense pulsed light, carboxy, electroporation and laser modular device for medical applications*

Modello/ *Model:*

MODULA CONTROL
MODULA RF
MODULA CV
MODULA IPL
MODULA TECAMED
MODULA CARBIOX
MODULA LD
MODULA EP
SONODIATERMIA-SOD

Tipologia/ *Typology:* **Apparecchiatura ad energia luminosa pulsata policromatica/** *Polychromatic pulsed light energy equipment*

Modello/ *Model:*

IPL LUX

L'organismo notificato
Notified Body

Data di ultima modifica: **20/05/2021**
Last revision date:

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Allegato tecnico al Certificato n° HD 60149156

Attachment to the certificate:

Tipologia/ *Typology:* **Apparecchiatura ad energia luminosa pulsata policromatica per medicina estetica/** *Polychromatic pulsed light energy equipment for aesthetic medicine*

Marca/ *Brand name:*

HAIRFREE

Modello/ *Model:*

INOSplus

Destinazioni d'uso/ *Intended use:*

Ipertricosi e irsutismo/ *Hypertrichosis and hirsutism*

L'organismo notificato
Notified Body

Data di ultima modifica: **20/05/2021**
Last revision date:

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TÜV Rheinland Italia S.r.l.

Allegato tecnico al Certificato n° HD 60149156
Attachment to the certificate:

TÜVRheinland®

Tipologia/ *Typology:* **Dispositivo medico attivo per il trattamento di patologie dermatologiche/** *Active medical device for the treatment of skin disease*

Modello/ *Model:*

Modula FLE

Codici/ *Codes:*

FLE

Destinazioni d'uso/ *Intended use:*

Trattamento dell'acne/ *Acne treatment*

Trattamento della rosacea/ *Rosacea treatment*

Rigenerazione cutanea e trattamento delle ferite/ *Skin and wound healing*

L'organismo notificato
Notified Body

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

Data di ultima modifica: **20/05/2021**
Last revision date:

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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

Wavemed S.r.l.
Registered and Operational Headquarter
Via della Comunicazione,4
00030 – San Cesareo (RM)

Attention:
Dott. Gavini Mirko

Date: 2024/06/21

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

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Dear Dott. Gavini,

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:

Wavemed S.r.l.
Registered and Operational Headquarter
Via della Comunicazione,4 -00030 – San Cesareo (RM)

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, about some device, the NB 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 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.

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

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E-mail:informazioni@it.tuv.com
Web:www.tuvitalia.com

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

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**
MODULA PLUS **Models/Variants:** **Modulo control** **Modulo IPL** **Modulo LD (Laser diodo)** **Modulo RF (Radio frequenza)** **Modulo Carbiox (Carbossiterapia)** **Modulo Cavitazione** **Modulo FLE** **Modulo EP** **BASIC UDI-DI:** **In definition**	IIb	MODULA CONTROL MODULA RF MODULA CV MODULA IPL MODULA TECAMED MODULA CARBIOX MODULA LD MODULA EP SONODIATERMIA-SOD Modula FLE	Certificate issued by TÜV RHEINLAND ITALIA S.r.l. Certificate No. HD 60149156 Annex II excl. point 4 Date of issue 10/06/2020 Date of expiry 26/05/2024
PIXI **BASIC UDI-DI:** **In definition**	IIb	N/A	Certificate issued by BUREAU VERITAS ITALIA S.p.A. Certificate Number

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

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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
			IT305915-1 Annex II escluso punto 4 Date of issue 22/03/2021 Date of expiry 26/05/2024
RFYNE **Models/Variants:** **Modulo RFYNE HEALTHCARE** **Modulo RFYNE AESTHETICS** **Modulo RFYNE GYNECOLOGY** **BASIC UDI-DI:** **In definition**	IIb	RFYNE	Certificate issued by BUREAU VERITAS ITALIA S.p.A. Certificate Number IT305915-1 Annex II escluso punto 4 Date of issue 22/03/2021 Date of expiry 26/05/2024

TUV RHEINLAND ITALIA (n.1936)

Ing. Lisa Menarini
Project Manager

Firmato digitalmente da Lisa Menarini

Annex:
Certificate No. HD 60149156 issued by TÜV RHEINLAND ITALIA S.r.l.
Certificate No. IT305915-1 issued by BUREAU VERITAS ITALIA S.p.A.

TÜV Rheinland Italia S.r.l.
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Membro del Gruppo
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