BUREAU VERITAS
Certification

ITALIAN ENGINEERING SRL

Via dell'Elettricista, 38 – 40138 BOLOGNA (BO) - ITALY

Certified site:

Via dell'Elettricista, 38 – 40138 BOLOGNA (BO) - ITALY

Bureau Veritas Italia S.p.A. certifies that the Full Quality Assurance System of the above organization has been audited and found to be in accordance with the requirements of

DIRECTIVE 93/42/EEC

(in accordance with Annex II - excluding paragraph 4)

In relation to the following products

Product subcategory :	Devices for hyperthermia / hypothermia
Generic group:	Radiofrequency device for medical therapy
Model:	ATTIVA; RFP COMPACT; RFP SMART; RFC-AM 01
Class:	IIb

Reference BV practice: ZIG. N. **9420812**

Original cycle start date: **24 November 2017**

Expiry date of previous cycle: **24 November 2020**

Certification / Recertification Audit date: **09 December 2019**

Certification / Recertification cycle start date: **27 January 2020**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **26 May 2024**

Certificate No. - Version: IT258067-3

Revision date: **21 May 2021**

GIORGIO LANZAFAME - Local Technical Manager

This certificate is issued by Bureau Veritas Italia S.p.A. Viale Monza, 347-20126 Milan, as a notified body for the Directive 93/42/EEC, with identification number 1370

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation.
To check this certificate validity please refer to the website www.bureauveritas.it

April 2nd , 2024

C/0272/24/GF/mm

To: ITALIAN ENGINEERING SRL
Via dell'Elettricista, 38
40138 - BOLOGNA (BO)

Bureau Veritas Italia SpA

Notified Body Confirmation Letter with reference to the CE Marking **Certificate n° IT258067 - 3 Directive 93/42/EEC (MDD)**

This letter confirms that, Bureau Veritas Italia SpA, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1370 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 n. n. 7949054 in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

ITALIAN ENGINEERING SRL
Via dell'Elettricista, 38
40138 - BOLOGNA (BO)
ITALY

Tabella n.1

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**Device name under MDD corresponding to the device under MDR application**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application**
Famiglia RFPAM02 modelli: ATTIVA RFP COMPACT RFP SMART RFC-AM01	IIb	Famiglia RFPAM02 modelli: ATTIVA RFP COMPACT RFP SMART RFC-AM01	Certificate n. IT258067-3 issued on 21/05/2021

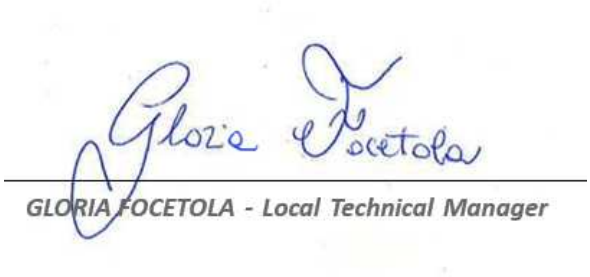
In accordance with EU Regulation 2023/607 of the European Parliament of the Council of 15 March 2023, Bureau Veritas Italia hereby confirms that:

a. The above-mentioned agreement n.7949054 was signed within 2024/09/26;
b. Bureau Veritas Italia Spa is responsible for the appropriate surveillance of medical devices certified under Directive 93/42/EEC and subsequent amendments, corresponding to medical devices for which an agreement has been signed for certification according to EU Regulation 2017/745 (MDR) as shown in table n.1

As required by EU Regulation 2023/607, the validity of the MDD certificate n IT258067-3**,** is extended until 2028/12/31, assuming that the manufacturer continues to comply with all the applicable conditions specified by EU Regulation 2023/607.

Confirmation Letter Revision History

Date	Revision	Action
2024/02/04	0	Initial issue



GLORIA FOCETOLA - Local Technical Manager

Bureau Veritas Italia S.p.A.
Viale Monza, 347
20126 Milano
www.bureauveritas.it

Tel. (+39) 02 27091.1
Fax (+39) 02 2552980
info.bv.italia@it.bureauveritas.com

Cap. Soc. € 4.472.131,00 i.v.
Reg. Imp. e P.IVA 11498640157
Altre Sedi: www.bureauveritas.it/sedi

Soggetta all'attività di direzione e coordinamento da parte di Bureau Veritas SA con sede in Neuilly-sur-Seine - Francia