EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

Certificate no. 052/MDR

On the basis of the assessment carried out according to the Annex IX chapters I and III of the Regulation (EU) 2017/745, we hereby certify that the full quality management system established, documented and implemented:

by the Manufacturer: **LED SPA**

03100 FROSINONE (FR) - VIA MARCO TULLIO CICERONE 138 (ITA) - Italy

SRN: IT-MF-000012232

for the following devices:

High frequency surgical equipment

Electrosurgical accessories

Equipment for CO2 gas supply

Equipment for diathermic therapy and related accessories

Electrotherapy equipments and electrostimulators and related accessories

Shockwave therapy equipments and related accessories

Therapeutic laser equipments and related accessories

complies and ensures the compliance of such devices with the applicable requirements of the aforementioned EU Regulation and it is subject to surveillance as required by the same Annex, section 3.

Further details are indicated in the Technical Attachment which is integral and substantial part of this certificate.

This EU Certificate is issued by IMQ S.p.A. as Notified Body no. 0051 for the Regulation (EU) 2017/745 related to medical devices.

Examinations and tests performed (references to applied common specifications and/or standard included) are documented in the relevant IMQ's conformity assessment Report, traceable through the IMQ's Project (indicated in the section "Revision history" below) and available on request.

First issue date:	2022-09-22
Previous issue date:	2023-05-30
Current issue date:	2023-07-27
Expiry Date:	2027-09-21

IMQ

Allegato Tecnico al Certificato UE n. 052/MDR

Technical Attachment of EU Certificate no. 052/MDR

Scheda tecnica n. 3

Technical sheet no. 3

Categoria di dispositivo:	**Apparecchi per terapia con CO2**
Device category:	*Equipment for CO2 gas supply*
Destinazione d'uso:	**Dispositivo medico attivo ad uso temporaneo e professionale, atto a regolare e controllare il gas inerte CO2 utilizzato per il trattamento terapeutico mediante somministrazione sottocutanea di: arteriopatie periferiche organiche e funzionali; pannocitosi Edemato-Fibro-Sclerotica (PEFS); adiposità localizzate; psoriasi; insufficienza venosa e linfatica; skin resurfacing (acne, dermatoporosi) o altro - trattamenti cutanei**
Intended purpose:	*Active medical device for temporary and professional use, designed to regulate and control the inert CO2 gas used for therapeutic treatment by subcutaneous administration of: organic and functional peripheral arteriopathies; Edemato-Fibro-Sclerotic Pannocytosis (PEFS); localized adiposities; psoriasis; venous and lymphatic insufficiency; skin resurfacing (acne, dermatoporosis) or other - skin treatments*
Classe di rischio:	**IIb**
Risk class:	IIb
Sito/i del Fabbricante / *Manufacturer's site(s):*	**- 04011 APRILIA (LT) - VIA SELCIATELLA 40 (ITA) - Italy**
Riferimenti ad altri certificati necessari per l'immissione sul mercato dei dispositivi in questione:	**Non applicabile**
Reference to other certificates required for the placing on the market of the covered devices:	*Not applicable*
Condizioni o limitazioni di validità:	**Nessuna**
Conditions for or limitations to the validity:	*None*
Altre informazioni rilevanti:	**Nessuna**
Other relevant data:	*None*
Dati dei dispositivi:	**I dati dei dispositivi sono elencati nel documento 'Elenco dei dispositivi oggetto del Certificato UE n. 052/MDR' rev. 3 del 2023/07/27 allegato al presente certificato. Tale documento costituisce parte integrante e sostanziale del presente certificato.**
Device data:	*Data of the devices are listed in the document 'List of the devices covered by the EU Certificate no. 052/MDR' rev. 3 dated 2023/07/27 attached to this certificate. This document is integral and substantial part of this certificate.*

Allegato Tecnico al Certificato UE n.052/MDR

Technical Attachment of EU Certificate no. 052/MDR

Storico delle revisioni

Revision history

N. *No.*	**Data** *Date*	**Riferimento Pratica IMQ** *Reference to IMQ Project*	**Descrizione** *Description*
1	2022-09-22	DM21-0073246-01	**Prima emissione** *First Issue*
2	2023-05-30	DM23-0086125-01	**Estensione per inserimento nuova categoria di dispositivo "Accessori per elettrochirurgia"; adozione dei nuovi template IMQ del certificato e del relativo allegato, senza alcuna modifica ai dati dei dispositivi** *Extension for additional new device category "Electrosurgery accessories"; adoption of the new IMQ templates of the certificate and related annex, without any change to the data of the devices*
3	2023-07-27	DM23-0090442-01	**Estensione per inserimento nuove categorie di dispositivi "Apparecchi per terapia con CO2", "Apparecchi per terapia diatermica e relativi accessori", "Apparecchi per elettroterapia ed elettrostimolatori e relativi accessori", "Apparecchi per terapia con onde d'urto e relativi accessori", "Apparecchi per terapia laser e relativi accessori"** *Extension for additional new devices categories "Equipment for CO2 gas supply", "Equipment for diathermic therapy and related accessories", "Electrotherapy equipments and electrostimulators and related accessories", "Shockwave therapy equipments and related accessories", "Therapeutic laser equipments and related accessories"*

Elenco dei dispositivi oggetto del Certificato UE n. 052/MDR

List of the devices covered by the EU Certificate no. 052/MDR

rev. 3 del of 2023/07/27

Marca/Marche Trade mark(s):	**G. TRADING COMPANY SNC**
Categoria di dispositivo: Device category:	**Apparecchi per terapia con CO2** Equipment for CO2 gas supply
Modello/i Model(s):	**VENUSIAN CO2**
Nome/i commerciale/i Trade name(s):	**come "Modello/i" /** as "Model(s)"