



SOFMEDICA GROUP

87-91, Calea Bucurestilor, 075100 Otopeni, Ilfov county, Romania

This is a multi-site certificate, additional site details are listed in the appendix to this certificate

Bureau Veritas Certification Holding SAS – UK Branch certifies that the Management System of the above organisation has been audited and found to be in accordance with the requirements of the management system standards detailed below

ISO 9001:2015

Scope of certification

Marketing, sales, import, storage, distribution of innovative life-saving medical devices and technologies and related spare parts. Technical support (installation, checking and preventive maintenance, emergency interventions, diagnosis, repairs, delivery and installation of spare parts). Clinical support and training for related medical devices and equipment. Provision, including translation of the information supplied by the manufacturer in order to market the medical devices (instructions for use and labels) and changing the pack size in order to market the medical devices).

Marketing, vanzare, import, depozitare, distributie de dispozitive si tehnologii medicale inovatoare, salvatoare de vietii si piese de schimb aferente. Suport tehnic (instalare, mentenanta, interventii de urgenta, diagnoza, reparatii, livrare si instalare piese de schimb). Suport clinic si training pentru dispozitivele, tehnologiile si echipamentele medicale distribuite. Furnizarea, inclusiv traducerea informatiilor furnizate de catre producator (instructiuni de utilizare, etichete) in scopul comercializarii dispozitivelor medicale si schimbarea marimii de ambalaj in vederea comercializarii dispozitivelor medicale.

Original cycle start date:	11-06-2018
Expiry date of previous cycle:	10-06-2021
Recertification Audit date:	29-04-2021
Certification cycle start date:	11-06-2021

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **10-06-2024**

Certificate No. RO2021.026.028Q

Version : NO. 1 Issue date: **13-05-2021**

Previous Certificate No. RO2018.069.027Q

Certification body address: 5th Floor, 66 Prescot Street, London E1 8HG, United Kingdom
Local office: Spitalul Unirii no. 165, TN Offices Building 3, Wing B, 5th Floor, Office 2, Bucharest, Romania

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 call: +40 21 3183800



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SOFMEDICA GROUP

ISO 9001:2015

Scope of certification

<u>Site Name/Location</u>	<u>Site Address</u>	<u>Site Scope</u>
Head Office: SofMedica S.R.L.	87-91, Calea Bucurestilor, 075100 Otopeni, Ilfov county, Romania	Marketing, sales, import, storage, distribution of innovative life-saving medical devices and technologies and related spare parts. Technical support (installation, checking and preventive maintenance, emergency interventions, diagnosis, repairs, delivery and installation of spare parts). Clinical support and training for related medical devices and equipment. Provision, including translation of the information supplied by the manufacturer in order to market the medical devices (instructions for use and labels) and changing the pack size in order to market the medical devices.
Site 1: SofMedica Hellas Medical Technologies S.A.	131 Kifissias avenue, 15124 Maroussi, Greece and Kifissias 119 Avenue Marousi 15124 Athens (warehouse)	Marketing, sales, import, storage, distribution of innovative life-saving medical devices and technologies and related spare parts. Technical support (installation, checking and preventive maintenance, emergency interventions, diagnosis, repairs, delivery and installation of spare parts). Clinical support and training for related medical devices and equipment. Provision, including translation of the information supplied by the manufacturer in order to market the medical devices (instructions for use and labels) and changing the pack size in order to market the medical devices.

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Scope of certification

<u>Site Name/Location</u>	<u>Site Address</u>	<u>Site Scope</u>
Site 2: SofMedica Cyprus Ltd.	31, Evagorou avenue, EVAGORAS COMPLEX Flat/Office 21, 1066 Nicosia, Cyprus	Marketing and sales of innovative life-saving medical devices and technologies and related spare parts. Technical support (installation, checking and preventive maintenance, emergency interventions, diagnosis, repairs, delivery and installation of spare parts). Clinical support and training for related medical devices and equipment.
Site 3: SofMedica Bulgaria EOOD	11, Gen. Shteryo Atanasov street, ground floor, office no.1, 1113 Sofia Municipality, Bulgaria	Marketing, sales and distribution of innovative life-saving medical devices and technologies and related spare parts; Technical support (installation, checking and preventive maintenance, emergency interventions, diagnosis, repairs, delivery and installation of spare parts); Clinical support and training for related medical devices and equipment. Provision, including translation of the information supplied by the manufacturer in order to market the medical devices (instructions for use and labels).

Certificate No. RO2021.026.028Q

Version : NO. 1 **Issue date:** 13-05-2021

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Certification body address: 5th Floor, 66 Prescott Street, London E1 8HG, United Kingdom
Local office: Splaiul Unirii no. 185, TN Offices Building 3, Wing B, 5th Floor, Office 2, Bucharest, Romania

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