



SOFMEDICA GROUP

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

The following site is part of the Management System of the above organisation:

SofMedica S.R.L.

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 vieti 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.

Certificate No. RO2021.026.028Q
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Previous Certificate No. RO2018.069.027Q

The validity of this certificate depends on the validity of the main certificate, which expires on: 10-06-2024



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Certification body address: 5th Floor, 66 Prescott Street, London E1 8HG, United Kingdom
Local office: Splaiul 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