



BUREAU
VERITAS

Bureau Veritas Certification

SOFMEDICA GROUP

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

This is a multi-site certificate, additional site(s) are listed on the next page(s)

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).

Original cycle start date:	11-06-2018
Expiry Date of Previous Cycle:	10-06-2021
Certification / Recertification Audit date:	29-04-2021
Certification / Recertification 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.: **R0001730** Version: **2** Issue date: **03-06-2022**

Signed on behalf of BVCH SAS UK Branch



0008

Certification Body Address: 5th Floor, 66 Prescott Street, London, E1 8HG, United Kingdom

Local Office: 165 Splaiul Unirii, Building TN Offices 3, B Wing, 5th Floor, Bucharest, 3rd District, 030133, Romania.

Further clarifications regarding the scope and validity of this certificate, and the applicability of the management system requirements, please call: +40213183800





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ISO 9001:2015

Scope of certification

Site Name/Location	Site Address	Site Scope
SofMedica SRL	87-91, Calea Bucurestilor, 075100, Otopeni, Ilfov county, Romania	<p>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.</p> <p>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.</p>

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SofMedica Bulgaria E00D	11, Gen. Shteryu Atanasov street, ground floor, office no.1, 1113, Sofia, Sofia Municipality, Bulgaria	<p>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.</p> <p>Маркетинг, продажби и дистрибуция на иновативни животоспасяващи медицински изделия и технологии и свързаните с тях резервни части. Техническа поддръжка (монтаж, проверка и профилактика, спешни интервенции, диагностика, ремонти, доставка и монтаж на резервни части). Клинична подкрепа и обучение за свързани медицински изделия и оборудване. Предоставяне на информация, включително превод на информацията, предоставена от производителя с цел предлагане на пазара на медицински изделия (инструкции за употреба и етикети)</p>

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SofMedica Cyprus LTD	31, Evagorou avenue, EVAGORAS COMPLEX Flat/Office 21, 1066, Nicosia, Cyprus	<p>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.</p> <p>Προώθηση και πώληση καινοτόμου ιατροτεχνολογικού εξοπλισμού και τεχνολογιών και των συναφών ανταλλακτικών. Τεχνική υποστήριξη (εγκατάσταση, έλεγχος και προληπτική συντήρηση, επείγουσες παρεμβάσεις, διάγνωση, επισκευή, διάθεση και εγκατάσταση ανταλλακτικών). Κλινική υποστήριξη και εκπαίδευση σχετικά με τον παρεχόμενο ιατροτεχνολογικό εξοπλισμό.</p>

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SofMedica Hellas Medical Technology S.A	131 Kifisias avenue and Kifissias 119 Avenue (warehouse), 15124, Maroussi, Athens, Greece	<p>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).</p> <p>Πρώθηση, πώληση, εισαγωγή, αποθήκευση, διανομή καινοτόμου ιατροτεχνολογικού εξοπλισμού και τεχνολογιών και των συναφών ανταλλακτικών. Τεχνική υποστήριξη (εγκατάσταση, έλεγχος και προληπτική συντήρηση, επείγουσες παρεμβάσεις, διάγνωση, επισκευή, διάθεση και εγκατάσταση ανταλλακτικών). Κλινική υποστήριξη και εκπαίδευση σχετικά με τον παρεχόμενο ιατροτεχνολογικό εξοπλισμό. Παροχή, συμπεριλαμβανομένης της μετάφρασης, των πληροφοριών που παρέχονται από τον κατασκευαστή με σκοπό τη διάθεση του ιατροτεχνολογικού εξοπλισμού (εγχειρίδια χρήσης και ετικέτες) και αλλαγή του μεγέθους της συσκευασίας με σκοπό την εμπορία των ιατροτεχνολογικών προϊόντων.</p>

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SofMedica Hungary Korlátolt Felelősségű Társaság (Kft)	Ráth György utca 56, 1122, Budapest, Hungary	<p>Marketing, sales, distribution of innovative life-saving medical devices and technologies for robotic surgery, surgical care, cardiovascular care, endoscopy, critical care, pulmonology and related spare parts; technical support (installation, checking, preventive maintenance, emergency interventions, diagnosis, repair, delivery and installation of spare parts); Clinical support and training for related medical devices, technologies and equipments.</p> <p>Marketing, értékesítés, innovatív életmentő orvosi eszközök és technológiák forgalmazása a robotsebészet területén, sebészeti ellátás, szív-és érrendszeri ellátás, endoszkópia, intenzív ellátás, tüdőgyógyászat és azzal kapcsolatos alkatrészek, technikai támogatás (telepítés, ellenőrzés, megelőző karbantartás, sürgősségi beavatkozás, diagnoszis, javítás, alkatrészek szállítása és telepítése); az orvosi eszközök, technológiák és felszerelések klinikai támogatása és képzése.</p>

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