



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 14001:2015

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 by another certification body:	07-05-2015
Expiry Date of Previous Cycle:	06-05-2021
Certification / Recertification Audit date:	NA
Certification / Recertification cycle start date:	07-05-2021
Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on:	06-05-2024

Certificate No.: R0001500	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





BUREAU
VERITAS

Bureau Veritas Certification

SOFMEDICA GROUP

ISO 14001:2015

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>

Certificate No.: R0001500

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





BUREAU
VERITAS

Bureau Veritas Certification

SOFMEDICA GROUP

ISO 14001:2015

Scope of certification

Site Name/Location	Site Address	Site Scope
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>

Certificate No.: R0001500

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

