

FAZZINI S.R.L.

S.S. PADANA SUPERIORE 317 - 20055 VIMODRONE (MI) - Italy

Certified site:

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Bureau Veritas Italia S.p.A. certifies that the Management System of the above organization has been audited and found to be in accordance with the requirements of the management system standards detailed below

ISO 13485:2016

Scope of certification

Design and manufacturing, placing on the market and after-sales service of active surgical devices (suction pumps), non-active intensive care devices (manual suction pumps), active breathing therapy devices (nebulizers), non-active emergency devices (immobilizers, endotracheal laryngoscopes, first-aid kits, stretchers), non-active orthopedic and rehabilitation devices (aids for the disabled and for rehabilitation), non-active devices (devices for hospital and ambulatory for the support and movement of the patient and accessories, stethoscopes), active devices for diagnosis (negativoscopes).

Commercialization and after-sales service of non-active devices with a measuring function (sphygmomanometers, scales), non-active devices for anaesthesia, emergency and intensive care (dressing and withdrawal accessories, balloons, breathing, anaesthesia and aerosol therapy accessories), non-active surgical instruments, active surgical instruments (electrocautery) active devices for monitoring (electrocardiographs monitors, scales), active devices for patient positioning and transport (operating tables), active respiratory devices (breathing accessories), active devices for disinfection and sterilization (sterilizers), active devices for monitoring (thermometers, blood pressure monitors), devices for electrosurgery, stimulation or inhibition (stimulators), non-active devices with a measuring function (thermometers).

Original cycle start date by another certification body: 02-July-2006

Expiry date of previous cycle: 14-June-2027

Certification / Recertification Audit date: 17-March-2025

Certification/Recertification Cycle Start date:

Subject to the continued satisfactory operation of the organization's

Management System, this certificate expires on:

Certificate No. IT341564 Version: 1 Revision date: 09-April-2025

GLORIA FOCETOLA - Local Technical Manager

ACCREDIA 5.

09-July-2024

14-June-2027

MS N° 0009MS

Certification Body Address:

Bureau Veritas Italia S.p.A., Viale Monza, 347 - 20126 Milan, Italy

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organization.

To check the validity of this certificate please double click or scan QR CODE

