EUROSETS EVERY LIFE MATTERS	**ENVIRONMENTAL AND QUALITY POLICY**	**QM-0019** **REV.003** **DATE 15/05/2024**

EUROSETS is a manufacturer of Medical Devices since 1976 and since 1998 was taken over by the Villa Maria Group headquartered in Lugo (Ravenna).

The **MISSION** entrusted to EUROSETS in this context is to design, develop and manufacture innovative devices to satisfy the requirements of the world market in the blood management sectors.

EUROSETS has an independent structure which guarantees the development, manufacturing, marketing and national and international distribution of its products.

EUROSETS TOP MANAGEMENT has focused its efforts on achieving and monitoring an integrated Management System which include Environment and Quality requirements according to **UNI EN ISO 13485: 2016 - Medical Devices and ISO 14001:2015.**

Organizational Structures and Operating Procedures are in force to ensure the effectiveness of the Integrated Management System and meet applicable regulatory requirements.

The **INTEGRATED ENVIRONMENTAL AND QUALITY SYSTEM** addresses all the corporate departments with the aim of involving and making the staff aware of their responsibilities in management of the technical, regulatory, organizational, administrative and human factors that have an impact on environment and quality.

FROM A QUALITATIVE POINT OF VIEW the main intention is to reduce, eliminate and, especially, prevent any qualitative shortcomings, steering towards preset standards of qualitative excellence with the main and paramount goal of safeguarding, maintaining and improving the health of the patient.

For this reason the following factors are considered fundamental to achieve the Eurosets' Quality Management System purpose:

- Safeguarding and improving the health of the patient
- Reducing and controlling the risks to which the patient and user may be exposed
- Customer satisfaction with the product supplied
- Conformity with the applicable standards and regulatory requirements
- Participation of all the staff
- Continuously striving for maximum competitiveness
- Collaborating with and supporting the customers in definition of the requirements
- Widespread participation in improvement of production
- Making everyone responsible for his / her work

FROM ENVIRONMENTAL POINT OF VIEW the main intentions is to ensure the performance of its activities in compliance with mandatory regulatory requirements, identify measurable environmental and continuous improvement objectives, minimize the impact of its activities on the environment, with particular attention to water consumption, waste and prevention of soil and air pollution, promote the efficient use of energy resources and the reduction of greenhouse gas emissions through the use of energy-efficient technologies and renewable sources and identify relevant interested parties needs and expectations.

For this reason the following factors are considered fundamental to achieve the Eurosets' Environmental Management System purpose:

- Make available adequate resources, economic means and expertise for the proper operation of the Management System and compliance with regulatory obligations;
- Develop procedures and instructions for defining how to manage activities with an impact on the environment;
- Provide for training and awareness-raising activities for personnel in the pursuit of environmental protection objectives;
- Plan and implement actions to reduce its environmental impacts (energy consumption, air emissions, waste, etc.).

TO SUPPORT THESE VALUES, MANAGEMENT ESTABLISHES MEASURABLE GOALS ANNUALLY. MANAGEMENT IS ALSO COMMITTED TO REVIEWING, DISSEMINATING AND ENFORCING THIS POLICY.

The EUROSETS Integrated Environmental and Quality Management System applicable standards regulation requirements are the following:

Document ID	Document Title
EN ISO 13485:2016 + A11:2021	Medical devices -- Quality management systems -- Requirements for regulatory purposes
EN ISO 13485: 2016	Medical Devices – Quality Management Systems. Requirements for Regulatory Purposes.
ISO 14001:2015	Environmental management system - Requirements with guidance for use
MDSAP	QMS certification for medical devices regulatory purposes
MDD 93/42/EEC	Medical Device Directive; Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices.
Directive 2007/47/CE	Directive 2007/47/CE and further amendments.
REGULATION (EU) 2017/745 (MDR)	REGULATION (EU) 2017/745 Of The European Parliament And Of The Council of 5 April 2017
FDA 21 CFR	Code of Federal Regulations, Part 803 Medical device Reporting Part 806 Medical devices; reports of corrections and removal Part 807 Establishment Registration And Device Listing For Manufacturers And Initial Importers Of Devices Part 820 Quality System Regulation;
SOR/98-282	Canadian Medical Device Regulation.
RDC No.16	Brazilian Resolution RDC No.16 (ANVISA).
Ordinance No. 169	Minister of Health, Labour and Welfare MHLW Ministerial Ordinance No. 169 - Pharmaceutical Affairs, Current Revision and further amendments.
JGMP Current Edition	Japanese Good Manufacturing Practices, Current Edition.
SFDA, Current Revision (China)	Regulations for Medical Devices of State Food and Administration, P.R.; China.
TGA ACT 1989 No. 21	AU - TGA - Therapeutic Goods (Medical Devices); THERAPEUTIC GOODS ACT
TG(MD) R 2002	Therapeutic Goods (Medical Devices) Regulations 2002
KGMP	Korea Medical Device Act and Related Regulation (equivalent to EN ISO 13485:2016)