

Quality Assurance Policy

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NOVAIR NOXERIOR GAS SYSTEMS considers quality a key element of its business strategy and promotes commitment to quality at all levels of the organization. For this purpose an internal Quality Management System (QMS) has been introduced, which complies with the standards of both UNI EN ISO 9001:2015 and UNI EN ISO 13485:2016. All employees of NOXERIOR have to operate conform the rules and procedures of the QMS as outlined in the Quality Manual of NOXERIOR.

The General Manager (AD/GM) promotes and supports the efforts to meet the requirements of the QMS and to maintain and continually improve the effectiveness of the same by emphasising the importance of information management to the entire organization of NOXERIOR providing the right information to the right person at the right time and risk analysis was carried out for all the critical departments of the company including the new NOXERIOR's facilities located in Via Genova n.5 at Grosseto – ITALY.

In order to assure greater product protection and best customer service, our management has decided to certify voluntarily its modular PSA nitrogen and oxygen generators with module H according to PED 2014/68 EU and as well to certify its medical devices placed on the market according to MDD 93/42 EEC class IIB (both issued by DNV third party notified body) and started with the (EU) MDR 2017/745 certification process.

The Quality Manual of NOXERIOR supplies the necessary instructions for the planning and implementation of actions for continuous involvement, training and updating of personnel at all levels of NOXERIOR's organization and in particular those engaged in activities related to quality.

The Quality Assurance Policy, defined by the General Manager and consistent with the general business policy and strategy of NOVAIR Group, establishes **and promotes** the following priorities:

- Compliance with Legal Requirements
- **Correctness in terms of the Branding Use**
- **Non misleading use of the QMS, product certifications and communication with the Customer**
- Customer Satisfaction
- Quality **improvement** of Products / Services
- Development of the Company
- Involvement of Employees
- Relation with Stakeholders
- Context analysis
- Risk analysis and opportunities
- Environment's respect



These priorities are translated into an annual plan with objectives and targets for each level of NOXERIOR's organization and with a clear definition of indicators and eventual programs and responsibilities for each objective.

The General Manager is committed to supply adequate resources and tools in terms of expertise, equipment, information, economic and financial resources for each defined objective and target and to monitor their suitability continuously, including the new NOXERIOR's facilities.

As decision making is based on data and information analyses, the General Manager promotes a methodological approach throughout the organization of NOXERIOR, which focuses on the systematic collection of data and its punctual analysis. Therefore, the General Manager has appointed the Quality Manager as representative of the Direction for the monitoring, maintenance and improvement of the QMS in accordance with the defined objectives. The Quality Manager may employ the services of qualified assistants. On a regular basis the Quality Manager will perform an audit of the QMS in order to verify the implementation and effectiveness in reaching the objectives and to arrange eventual corrective actions and improvements.

The AD/GM agrees to review the adequacy of the QMS according to Sections of NOXERIOR's Quality Manual at least one time per year and to provide guidance on the eventual necessary corrections and / or improvements to the structure of the same. During these reviews he will also verify real values against the defined annual quality objectives and discuss eventual deviations. The Quality Assurance Policy will also be reviewed periodically (at the time of the review of the QMS and in conjunction with changes in the QMS) and revised when necessary. To facilitate the distribution and understanding of the Quality Assurance Policy, the AD/GM will meet with line managers on a regular base in order to increase the awareness of the role of each individual in the organization of NOVAIR NOXERIOR GAS SYSTEMS.

NOXERIOR s.r.l.
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