



## QUALITY AND ENVIRONMENT POLICY

*Our quality goal is to offer products that:*

- *Meet customer expectations.*
- *Conform to the most relevant national and international standards.*
- *Constitute a market niche that provides us with satisfactory profit margins.*

*These expectations and requirements must be turned into objectives at all levels of the company.*

*We do not accept to produce products that do not comply with the required specifications and applicable regulations.*

*This implies that:*

- ↺ *Our products are manufactured according to applicable national and international quality standards and meet applicable legislative requirements (e.g. DDM 2007/47/EC, MDR 2017/745 etc.).*
- ↺ *The company's Quality and Environment System is organised in such a way as to meet the requirements:*
  - ↺ *Of DDM 93/42/EEC (and subsequent updates), of MDR 2017/745 (for the parts to be transposed from 26/05/2021);*
  - ↺ *Of the UNI CEI EN ISO 13485:2016 standard which specifies the requirements for QMS enabling DIMAR to demonstrate its ability to supply medical devices that comply with customer and applicable regulatory requirements;*
  - ↺ *Of the UNI EN ISO 14001:2015, which specifies the requirements for implementing the EMS.*
  - ↺ *Our suppliers are selected according to their ability to meet our specific needs and are appropriately qualified.*
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- ↺ *Our products are designed to be safe for the patient and the user and therefore must:*
  - ↺ *Comply with all limits required by the application of international standards;*
  - ↺ *Remain safe under normal operating conditions, under reasonably foreseeable operating errors and also under single fault conditions, including software failures;*
  - ↺ *Present "acceptable" residual risks; after application of the risk control measures and even if they present significant residual risks, these shall not be significant when compared to the clinical benefit provided by the products and the clinical state of the art in the reference market.*
- ↺ *All personnel are adequately trained and prepared.*
- ↺ *We consider any complaint or non-conformity by the customer or by our internal or external collaborators as a moment of professional growth since it allows us to continuously improve the quality of our service and our management and organisational system.*
- ↺ *The QMS is organised in such a way as to trigger appropriate corrective and preventive actions in order to ensure that its effectiveness is maintained, and in such a way as to monitor the aspects deemed critical to ensure the adequacy of the processes carried out in the company and of the Medical Devices to the demands of the market and users and to the requirements of the applicable standards and directives. All processes are managed according to a risk management approach.*

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- ↪ *The processes carried out in the company are planned in such a way as to guarantee maximum flexibility of the service offered, compliance with the required delivery times at a cost compatible with market expectations, and fulfilment of the mandatory requirements of the applicable directives and standards. In order to combine quality and environmental sustainability, we are also committed to protecting the environment through the following guidelines:*
- ↪ *We ensure compliance with current environmental laws and regulations, considering them the starting point for continuous improvement.*
  - ↪ *We prevent and reduce pollution due to discharges, waste and emissions by directly implementing and enforcing environmental management principles at all levels of the company organisation and external collaborators.*
  - ↪ *We optimise the production cycle to minimise waste and waste generation.*
  - ↪ *We constantly monitor the consumption of resources in order to avoid waste where possible, working to improve the performance of facilities and plants by adopting appropriate internal management measures.*
  - ↪ *We make suppliers aware of environmental issues.*
  - ↪ *We constantly inform, sensitise and involve our personnel through appropriate training so as to make them not only participants in the project but also the main subject, since environmental issues concern everyone and require that everyone makes them their own.*
  - ↪ *We ensure the prompt and transparent communication of relevant information within the organisation and externally*

*The organisation places the needs and expectations of its customers and purchasers at the forefront, setting as one of its objectives for pursuing success the implementation of adequate instrumental and economic resources and, above all, placing great value on the contribution made by the human resources engaged in the realisation of business objectives. The protection of workers in terms of health and safety and professional growth is a topic of great centrality in the development plan defined by the organisation.*

*In defining its objectives DIMAR orients its vision towards a perspective of 'responsible quality', according to which customer satisfaction can be significantly increased by the organisation's attention to the community and other players in the internal and external context.*

*DIMAR is committed to maintaining the Integrated Management System in conformity with the requirements of UNI EN ISO 13485:2016 and UNI EN ISO 14001:2015 standards, promoting an ever greater diffusion and integration of the system's procedures in the company's organisational and managerial reality and assigning proportional responsibilities to each person belonging to it. To guarantee the effective maintenance of the Integrated Management System, the organisation has given itself an efficient and flexible production structure, activating continuous monitoring over the entire production chain and extending quality control also to outsourced processes.*

*The organisation, in achieving its strategic objectives, is committed to satisfying workers and other stakeholders:*

- *By providing a safe and healthy working environment;*
- *By sharing the organisation's strategic objectives with internal staff;*
- *By offering workers continuous training with the aim of increasing their skills and expanding their know-how;*
- *By implementing communication and participation processes that make the worker an active part of the company's improvement and growth and by transmitting the necessary tools to prepare them for the rapid changes imposed by the market;*



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- *By favouring collaboration, communication and dialogue with all stakeholders (institutions, trade unions, shareholders, suppliers, etc.) with a view to transparency.*

*To put this into practice and reaffirm its commitment, Top Management:*

- ✓ *Adopts an approach based on the analysis of risks and opportunities referred to each process, in order to define corporate strategies in terms of quality and OSH;*
- ✓ *Undertakes to provide the human, instrumental, economic and documentary resources necessary to achieve the objectives set;*
- ✓ *Ensures that all workers receive adequate information and training, that roles are clearly defined and that everyone is sensitised to perform their tasks in compliance with current regulatory requirements and internal requirements set by the organisation;*
- ✓ *Is committed to reviewing the context within which it operates, focusing on recent and future changes in the global socio-economic system and renewing its objectives according to the demands of all stakeholders, always putting the health protection aspects of workers and the community first;*
- ✓ *Updates the documented information of the Integrated Management System in order to ensure its continuous adequacy and effectiveness;*
- ✓ *Undertakes to disseminate and foster understanding and sharing of the policy and its objectives with all interested parties;*
- ✓ *Ensures that the company structure (managers, supervisors, designers, plant engineers, purchasing office, production operators, etc.) participate according to their attributions and competences in achieving the IMS objectives with a view to continuous improvement and preparation for controllable external changes.*

*With the dissemination of this Policy document, the Management asks all interested parties for their utmost commitment to pursuing the objectives stated herein, acknowledging that the quality of products and safety in the company are the result of a choral and daily work*

*Medolla, 19/05/2022*

*The Plant Manager  
Mr. Maurizio Borsari*

DIMAR S.r.l.  
a Socio Unico  
Via Galilei n. 6  
41036 MEDOLLA (MO)  
C.F. e P. IVA 02779340369