

	<h2>Quality Policy</h2>	<p>DOC 5.3-01 Pag. 1 of 2 Rev.6 del 04/08/2023</p>
---	-------------------------	--

## QUALITY POLICY

Hyper Photonics s.r.l. Management decided to introduce in the company a certified quality management system, in order to demonstrate its ability to regularly provide products and services that meet customer's requirements, the applicable mandatory requirements and customer satisfaction.

The reference standards to comply with are UNI EN ISO 9001:2015 (quality management system – Requirements), UNI CEI EN ISO 13485:2021 (Medical devices – quality management system - requirements for regulatory purposes) and CFR Title 21 Part 820 (Quality System Regulation), 803 (Medical Device Reporting), 806 (Reports of Corrections and Removals), 807 (Establishment Registration and Device Listing).

Hyper Photonics s.r.l. quality policy comes from the analysis of the internal and external context of the organization, which are the main components that have been considered. Each of the identified macro-categories corresponds to appropriate business processes aimed at concretely implementing the general strategies.

The consideration of the main interests of the main interested parts has led to the formulation of schemes and relationship between the context and the interested parts with the aim to define the main processes and the related targets.

The management of our main processes and of the influences determined by company contexts and by the interested parts is based on the analysis of the related risks according to the guidelines of the standard UNI 31000:2018 (risk management – principles and guidelines).

The application field of Hyper Photonics S.r.l. quality system management for standard UNI CEI EN ISO 13485:2021 concerns activities of:

***“Service of laser equipment and related handpieces for the medical industry”.***

The main quality objectives are the following:

- a) to achieve and maintain the quality of the product and of the provided service such that it continuously meets customer and interested parts requirements, the applicable mandatory requirements (in particular the standard 93/42 CE for the product and the standards 9001:2015, 13485:2021 and CFR Title 21 Part 820 for the system), customer and stakeholders' satisfaction.
- b) to pursue continuous improvement in the conduct of business, so that this improvement is perceived by customers in terms of greater satisfaction with the products and services provided;

c) to achieve, maintain and control a certain quality in the design and manufacture of the product in accordance with the indications of Annex IX of the Regulation EU 2017/745;

d) to guarantee customers and all interested parties the safeguarding and protection of personal data of a sensitive or judicial nature, observing the principles of confidentiality, integrity and availability of data, dictated by the "Data Privacy Code" (Legislative Decree 196/2003 and subsequent amendments and European Regulation on data protection 679/2016);

e) to ensure an effective degree of communication of this corporate policy statement, using suitable tools and methods. The recipients of this communication also include the interested parties, the people of the organization and the most contiguous subjects of the context.

The periodic review of the management re-evaluates the principles and perspectives expressed in this document, reformulating the contents if necessary.

A correct development of the communication process implies the knowledge, the involvement and the contribution of each function and person of the organization, within the scope of its competences, to the implementation and achievement of the defined objectives.

Concorezzo (MB), 04/08/2023

The Legal Representative