QUALITY POLICY STATEMENT

PRIM, a company engaged in the manufacturing of orthotic and orthopaedic products, as well as in the distribution and technical service of medical devices, also committed to the manufacturing, distribution and after-sales service for rehabilitation and physiotherapy devices, declares that quality is a priority in the development of their activities, in order to meet customer needs anytime, by offering them a competitive product, by involving in these processes every company department and their personnel.

PRIM SA Quality System complies with all applicable requirements described in the **EN ISO 13485:2018,** standard**.**
The certified scope applies to:

- **Design, manufacturing and distribution of orthoses, orthopaedic devices and rehabilitation and physiotherapy equipment.**
- **Distribution and technical support of medical and non-medical devices.**
- **Grouping of CE marked medical devices for procedure packs.**

The guidelines and general objectives related to quality assurance, to which PRIM is committed to, are unified and described in their Quality Policy Statement, which is defined by Head Direction as part of the general policy of the company and consistent with it.

Our Quality guidelines are:

- Commitment to meet the requirements of the interested parties and maintain the efficiency of the QMS.
- Make sure that the products and services provided to the customers are safe, reliable and meet all the specifications, standards and codes which apply to them.
- Work and collaborate closely with customers in the improvement of our products and services.
- Settle actions and programs not only focused on the detection and correction of non-conformities but aimed at prevention
- Measure and analyse all the data related to Quality processes to attain and maintain a continuous improvement in the organization.
- Comply with the applicable statutory and regulative requirements related to service and sales, and with the specific relevant to the context of the organisation and stakeholders.
- Develop projects to improve our products and services, from a technological and quality point of view.
- Educate, motivate and involve the entire staff working on behalf the company in the management and development of the implemented Quality Management System.

In order to implement these Quality Policy statement, PRIM carries out their management based on the following standards and directives:

- Regulation (EU) MDR 2017/745 concerning medical devices and (EU) 2017/746 in vitro diagnostic medical devices.
- EN-ISO 13485:2018. Medical Devices. Quality Management Systems Requirements for regulatory purposes.

This statement will be reviewed every year and will be updated whenever the changes require a new document.

This statement provides the framework to settle and review the objectives and targets of this management system and it’s appropriate to the purpose and context of the organization.

This Policy will be made available to interested parties by defining the channels of communication.

PRIM’s Management shows its engagement by means of this statement and takes responsibility for its understanding, implementation and continuous updating at every level of the company.

(*)Document excerpted from PRIM Quality Manual, 22nd revision January 2025, paragraph 5.3.1