

## PROCEDURES

### Quality Policy

The vision of Nidek technologies is:

“To design and develop innovative, technologically advanced equipment and software systems for diagnostic ophthalmology. To provide the mother company with functional models of such equipment and software. To manufacture and service such products with the highest standard and care of customer’s satisfaction” .

Nidek Technologies has the role of manufacturer according to MDR 2017/745.

MD shall use the Quality Policy as a means of leading the organization toward improvement of its performance.

The organization's Quality Policy is an equal and consistent part of the organization's overall policies and strategy.

The organization pays extreme attention to meeting environmental requirements and uses an environmental management system that enhances the environmental performances as required by the International Standard

In establishing the Quality Policy, MD considers and communicates to the organization personnel (mainly during the “internal meetings”, see P 05 Management Responsibility procedure):

- the level and type of future improvement needed for the organization to be successful,
- the expected or desired degree of customer satisfaction,
- the development of people in the organization,
- the needs and expectations of other interested parties,
- the resources needed to go beyond ISO 9001 and 13485 requirements,
- the new or changes regulations
- the potential contributions of suppliers and partners
- the commitment to maintain the effectiveness of the quality management system

The Quality Policy is used for continual improvement provided that:

- it is consistent with MD’s vision and strategy for the organization's future,
- it permits quality objectives to be understood and pursued throughout the organization,
- it demonstrates MD’s commitment to quality and the provision of adequate resources for achievement of objectives,
- it aids in promoting a commitment to quality throughout the organization, with clear leadership by top management,

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- it includes continual improvement as related to satisfaction of the needs and expectations of customers and other interested parties,
- it is effectively formulated and efficiently communicated.

As with other business policies, the quality policy is periodically reviewed during the NT management review meetings.

The organization is committed all-round in a continuous improvement process in order to attain superior quality objectives. Each organization function is committed towards constantly satisfying the requirements of all the organization's customer. All the organization's employees and suppliers are given all the necessary assistance and, where possible, stimulated in order to obtain continuous quality improvement.

The products and services supplied and activities performed by each employee must in all ways and at all times meet the requirements which satisfy NT internal and external customers.

All the organization's employees and suppliers undertake to prevent any errors, whether these relate to performance or management, as well as to correct the same, with the full knowledge that prevention is much less expensive than correction.

All the organization's employees and suppliers undertake to update the ways and means of satisfying the requirements of NT customers and to constantly follow up the development of the same.

Each organization function manager has the task of:

- establishing and maintaining suitable conditions for contributing towards the design, development and production of products at a high technological level;
- establishing and maintaining suitable procedures for carrying out the checks necessary for the realization of such products;
- organizing suitable training programs in order that each person is qualified enough to assume his/her own responsibilities;
- providing an internal check and revision system in order to ensure that the spirit and the message of this policy are maintained.