Hearing Aids Quality policy

December 2022

Demant

The Quality policy is **embedded in our decision-making** and ways of working.

It reflects **our intentions** regarding the quality of our products and **services to deliver the best to our customers and users**.

The policy covers activities supporting product development, manufacturing, marketing and servicing. It applies to the following brands: Oticon, Bernafon, Sonic and Philips Hearing Solutions.

We want to be the preferred hearing aid manufacturer in the market in terms of products and services

Reliability and compliance

Our products meet user expectations for **safety and effectiveness throughout the expected lifetime of the instrument** while complying with regulatory requirements, such as EN ISO 13485:2016, Medical Device Directive 93/42/EEC (MDD), Medical Device Regulation 2017/745 (MDR), FDA 21CRF Part 820, local countries regulatory requirements and MDSAP requirements

Audiological performance

Hearing Care Professionals experience that the product **effectively helps users overcome hearing loss** taking the product price and performance option into consideration. We are customer-focused, and we understand their pains and gains. Our human performance claims are always going through a standardised review and approval process by a dedicated committee before being disseminated.

Design

Users experience a high-quality product which is **attractive, small and easy to use**

Connectivity

We aim to give users **high quality experience** for any approved connected Demant and non-Demant accessory

Continuous improvement

Through on-going market data analysis and customer/user feedback, we work towards improving **our products, services and processes.**

Accountability

Each function within the company is accountable for the quality of their deliveries.

The Quality function is accountable for assuring that quality & compliance is delivered by the organisation.
The Quality function is empowered to request plans and activities for quality improvement

Responsibilities

Demant Management carries the overall responsibility of product quality and safety, and specific managerial responsibilities are defined and described for relevant activities. Ahead of any product entering the market, the quality and safety is documented, and key documents of the final product are reviewed and approved by Management.

Quality Management System

Our Quality Management System (QMS) demonstrates our ability to offer medical devices which consistently meet customer needs and comply with regulatory requirements.

Products are tested against reliability requirements, which are defined during the process of product development. Requirements are based on standards, regulation and our extensive experience with manufacturing hearing aids. At the end of the development process, final verification test production equivalent products to secure safety and effectiveness.

Extensive reliability testing ensures that a product is safe and effective during a its lifetime, and we test on competent, assembly and product level. Internally, the system is audited by our audit team and maintained to reflect development and changes of our organisation.

In case of an incident, we assess if it classifies as reportable to relevant health and/or national authorities. Our QMS requires a dedicated procedure to ensure proper coordination and action based on authority regulations.

CAPA

In case of an incident, it will be handled in our CAPA (corrective and preventive action) system through which we conduct methodical risk analysis, root cause analysis, corrective actions and prevent the issue from reoccurring. To do so, dedicated resources with relevant competencies are immediately allocated to the task.

Handling complaints

The complaints are handled in our compliant system and processed in a uniform and timely manner.

Our procedures ensure that all complaints on products marketed and sold are registered, evaluated and investigated. Monthly, we identify any trending complaints.

In case of a deviation of the quality target in question, Demant Management is informed.

Training employees

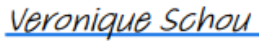
We ensure that all employees are trained in processes relevant to their tasks. Managers establish employee training plans to secure relevant training ahead of any critical quality or safety activities.

The training is documented, and we evaluate training performance and effectiveness. Employees involved with our Quality Management System are per default trained, and their 'Read and Understood' trainings are recorded.

Reporting

We report annually on our quality efforts through Demant's Sustainability report.

Veronique Schou, Senior Vice President, Quality, Hearing Instrument Group



December 2022