Quality policy

Diagnostics

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 in our Diagnostics business. It applies to the following brands Maico, Interacoustics, Amplivox, Grason-Stadler, AudioScan, Inventis and MedRx.

We want continuously to be the preferred supplier of diagnostics solutions in the market in terms of products and services

Reliability and compliance

We supply products and services in compliance with regulatory requirements and which meet the requirements and expectations of the users

Audiological performance

We meet expectations and needs of our customers and users, who experience that the products and services effectively detect and screen hearing loss

Design

We design and develop innovative and high-tech solutions for the global market

Risk management

We review the risk management activities and ensure the risk management process is efficient

Continuous improvement

Through on-going market data analysis and customer/user feedback, we strive for efficiency in our processes and improve quality performance in our processes, products, and services

Accountability

Each function is accountable for the quality of their deliveries.

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

How we work

Responsibilities
Diagnostics management carries the overall responsibility for quality and safety of Diagnostics products and services.

At least once a year, management establishes, communicates, and reviews measurable quality targets while ensuring adequate skills, tools, materials, workplaces, and other resources to deliver on them.

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

Product design
When we design new products, we gather information about customer needs, product requirements and procedures and apply risk management throughout the entire product life cycle. We work with suppliers that can deliver parts and services in the required quality, monitor supplier performance, and give supplier feedback as appropriate.

Testing
When our engineers and specialists develop new instruments and accessories they collaborate with external researchers and medical professionals. Before release, products are extensively tested in accredited test houses and verified according to state-of-the-art performance standards.

Manufacturing
When we manufacture diagnostic instruments, we have processes in place to test and verify products according to specifications. We use only suitable production and test equipment which are calibrated and essential.

We do a 100% test and final inspection of our products to make certain that they comply with and fulfil specifications. We ensure proper corrective action and investigation and always begin testing with a risk assessment.

Improvements
To improve the quality level of a product or service, we regularly monitor customer satisfaction and collect and evaluate customer feedback.

We perform internal audits, monitor the efficiency of manufacturing processes and the performance of products prior to release. We record and analyse information on non-conforming products and implement corrective and preventive actions as necessary to maintain or improve the level of quality.

Handling complaints
All complaints are handled in our complaint 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, 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.

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

Flemming Vinding, Vice President,
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