INTRODUCTION

The International Electrotechnical Commission (IEC) is an international standards organisation that prepares and publishes international standards for all electrical, electronic, and related technologies.

Any device designed, developed, and used as a medical device for audiometry/acoustics should comply with the requirements of the **IEC 60645** standard.

IEC 60645 is a standard with different parts addressing a specific set of audio devices and their compliance. Below are the applicable parts that are in scope for this case study:

- IEC 60645-1: Electroacoustics - Audiometric equipment - Part 1: Equipment for pure-tone and speech audiometry
- IEC 60645-3: Electroacoustics - Audiometric equipment - Part 3: Test signals of short duration
- IEC 60645-6: Electroacoustics - Audiometric equipment - Part 6: Instruments for the measurement of otoacoustic emissions
- IEC 60645-7: Electroacoustics - Audiometric equipment - Part 7: Instruments for the measurement of auditory brainstem responses

BACKGROUND

Our client is a leading manufacturer and service provider that offers medical devices and the relevant accessories and software, as well as services for diagnosis, monitoring and treatment of impairments and disorders that affect newborns, the brain, nerves, balance and hearing. The client's medical devices, like the **newborn hearing screener,** are used in hospitals, medical clinics and laboratories in many different regions.

The client's **newborn hearing screener** is a portable and lightweight alternative to larger cart-based systems with different specifications. It is a handheld device that combines an **otoacoustic emissions** (OAE) screener with an **auditory brainstem response** (ABR) screener. It is used both during in-hospital screening and at non-hospital births and screening sites.

CHALLENGE

The client had to prepare, implement and update its existing audiometric device requirements and test cases according to the IEC 60645 standard for devices like the newborn hearing screener.

The client needed to update the requirements and develop test cases according to the IEC standards within a specific time frame. Failure to do so would have resulted in non-conformity, impacting sales and the credibility of the product.

SOLUTION

We studied the IEC standards and identified relevant clauses for the product in question. We then developed a sophisticated checklist to map and draft the requirements. The checklist was presented to a technical team comprising product SME, labelling SME, hardware, firmware and software design teams to review and confirm the applicable IEC standard clauses. Later we used the checklist to develop verifiable test cases for each finalised requirement.

Verifying each requirement was the next step. This involved considering the testability of the requirements and developing rationale for the non-testable requirements. We also delegated testable requirements to the respective labs and test facilities involved. We drafted the process and divided it into the 4 sections shown in the figure below, to keep track of the status of every section. This allowed us to check the verifiability of a requirement at the end of each section.

BENEFITS DERIVED

- This process helped the client meet the compliance requirements within the stipulated time frame and avoid non-conformity. Since there was no major hinderance, sale of the devices continued.
- Reusability of the approach in similar situations.

Decos provides services in the area of product standardisation to ensure regulatory compliance for all kinds of requirements such as firmware, and user and product requirements, etc.