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TECHNISCHE HOCHSCHULE LÜBECK

Master thesis

Author: Ratul Hassan
Supervisor: Prof. Dr.-Ing. Dipl. Ing. Stefan Müller
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Topic: Implementation of a Risk Management System for a new Blood Gas Analyser according to the In-vitro Diagnostic Regulation (IVDR) – (Regulation (EU) 2017/746)

Summary:

The thesis, "Implementation of a Risk Management System for a New Blood Gas Analyser According to the In-Vitro Diagnostic Regulation (IVDR)," describes the creation of a structured risk management framework to ensure the safety, quality, and regulatory compliance of a new blood gas analyser in the medical device industry, an essential diagnostic tool in critical healthcare settings. This device, which is utilized to evaluate a patient's respiratory and metabolic status via gaseous parameters in blood like O_2, CO_2, PCO_2, Ph. Which required to be adhered to the stringent European Union IVD Regulation (EU) 2017/746, which regulate In Vitro Diagnostic (IVD) devices. The study proposes a lifecycle-based approach to mainly risk management with encompassing design, and the identification and mitigation of potential risks that could potentially impact patient safety, device performance, or regulatory compliance. The thesis systematically evaluates potential device failures, ranks their severity, and implements risk control measures to address identified hazards by utilizing ISO 14971:2019 (supported by ISO/TR 24971) for risk management and ISO 13485 for quality management.

The methodology starts with a detailed literature and regulatory review to understand EU requirements for blood gas analysers, followed by systematic risk identification and evaluation through both FMEA & ISO 14971:2019. This process includes a "Risk Management Plan for Blood Gas Analyzer" establishes a methodology for identifying, evaluating, and managing risks associated with the device throughout its lifespan, thereby guaranteeing safety and regulatory compliance. A multidisciplinary team employs tools such as FMEA & ISO 14971:2019 standards to compare and evaluate hazards, prioritizing controls through design safety, protective measures, and user information. Risk controls are evaluated for their efficacy, and risks are categorized to determine if further mitigation is necessary. The plan includes continuous updates based on any inputs, in accordance with ISO 14971:2019.

Defining different hazards & risks, such as device malfunction, inaccurate measurements, possible user error or labelling error, and risk scenarios across the device's intended use for a blood gas analyser has been followed, after establishment of the risk management plan. Based on seventy-four different categorized risks, risk control measures are created and implemented into the device's design, usability, and operational protocols during the development and production phase. The study demonstrates that a robust quality management system aligned with ISO 13485 is key to supporting risk management practices, documenting control processes, and enabling continuous improvement. Verification and validation of the risk management system are conducted through testing, usability analysis, and practical application to confirm the system's effectiveness in minimizing residual risks and ensuring regulatory compliance.

The Risk Management File and Report for the blood gas analyser has been established in accordance with the ISO 14971:2019 (supported by ISO/TR 24971) framework. It documents the entire risk management process, including identified risks and evaluations, control measures, and verifications to ensure regulatory compliance and safety across the device's lifecycle.

The thesis concludes with an evaluation of the risk management system's success in meeting In-vitro Diagnostic Regulation (IVDR) – (Regulation (EU) 2017/746) requirements, significantly reducing potential risks, and contributing to the overall safety and performance of a new blood gas analyser. By aligning with the latest regulatory and industrial standards, the findings offer a valuable framework for future research and development of this new blood gas analyser. This work provides both theoretical and practical guidance for the blood gas analyser manufacturer on implementing risk management processes that not only fulfil regulatory demands but also enhance patient safety and device reliability in critical diagnostic applications.