

# ISO 13485:2016

Norme Deutsche DIN EN ISO 13485:2016-01-01  
 Medizinprodukte – Anforderungen an Qualitätsmanagementsysteme  
 Medical devices – Requirements for quality management systems  
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 Normennummer: 13485:2016

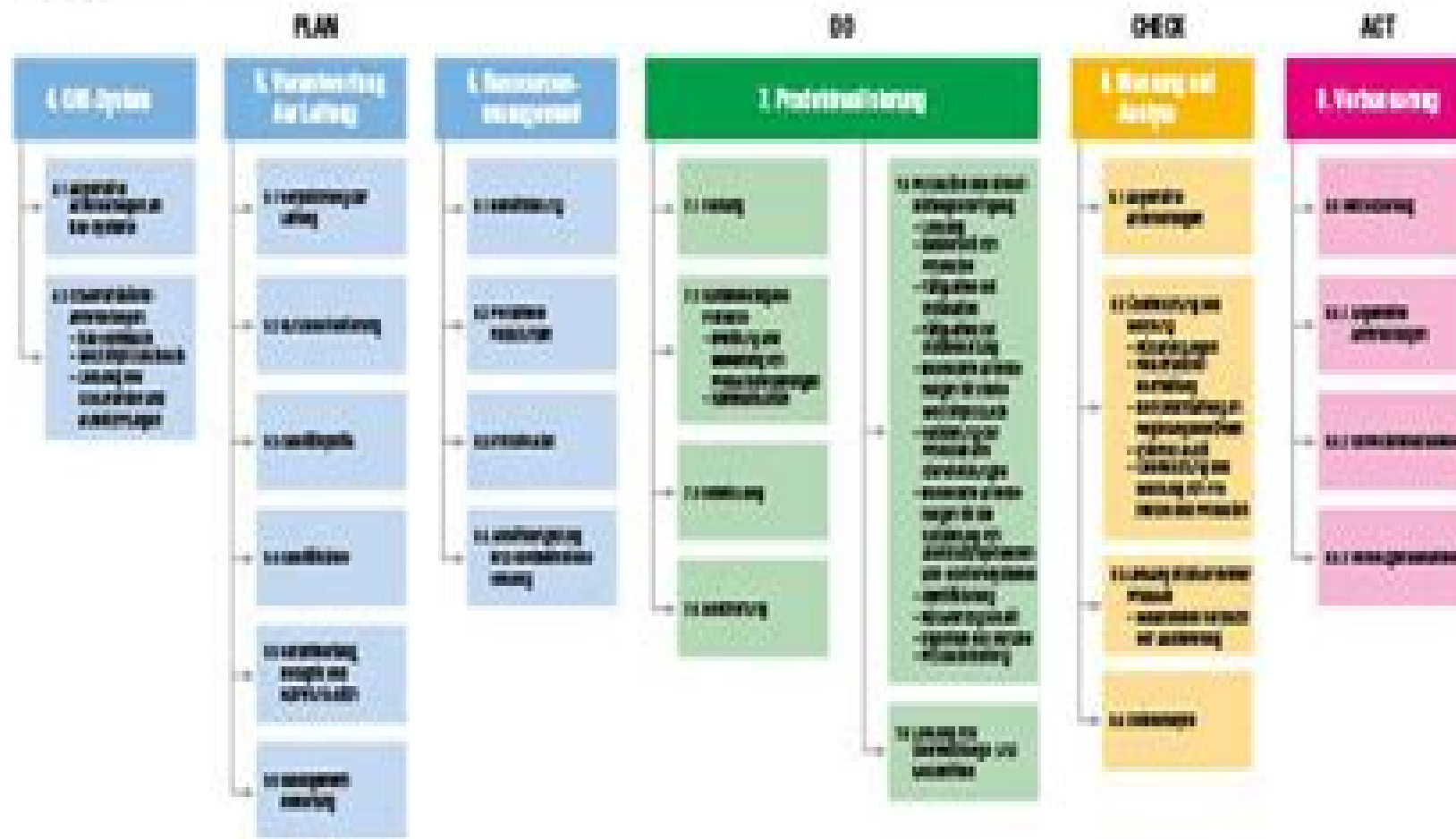


Product

1. Anwendungsbereich

2. Normative Verweisungen

3. Begriffe



# Iso 13485 2016 Revision Factsheet Tuev Sued

**Polska. Polski Komitet Normalizacyjny**

## **Iso 13485 2016 Revision Factsheet Tuev Sued:**

*A Practical Field Guide for ISO 13485* Erik V. Myhrberg, Joseph A Raciti, 2019-11-06 The purpose of this expanded field guide is to assist organizations step by step in implementing a quality management system QMS in conformance with ISO 13485 2016 whether from scratch or by transitioning from variations of the ISO 13485 family In keeping with ISO 9000 2015 s definition of quality as the degree to which a set of inherent characteristics fulfills requirements Myhrberg Raciti and Myhrberg have identified the requirements and inherent characteristics distinguishing features for this expanded field guide Within the guide each subclause containing requirements is the focus of a two page visual spread that consistently presents features that fulfill the requirements listed below This guide will Provide a user friendly guide to ISO 13485 2016 s requirements for implementation purposes Identify the documents documentation required along with recommendations on what to consider retaining adding to a QMS during ISO 13485 2016 implementation Guide internal auditor s regarding what to ask to verify that a conforming and effective QMS exists Direct management on what it must do and should consider to satisfy ISO 13485 2016 s enhanced requirements as well as on the responsibilities for top management Depict step by step in flowchart form what must occur to create an effective conforming QMS **ISO 13485 for Engineers** Priscilla Browne, 2021-12 This book is written to provide Quality engineers medical engineers device engineers with a practical and insightful companion to understand ISO 13485 Quality Management system for medical devices It provides a straight to the point perspective which should assist in the interpretation of the standard and provide a benchmark for what is expected in the application of the standard and compliance for industry ISO 13485 2016 is an international standard for the quality management of medical devices It is of value and applicable to a number of business areas that are involved in the various stages of a medical device and its product lifecycle It may be applied by a design company manufacturer raw material supplier calibration service sterilization services or distributor The scope of the standard covers design and development production storage and distribution installation servicing if required decommissioning and disposal In particular manufacturers of medical devices and typically mandated by regulatory bodies to comply with ISO 13484 and must demonstrate compliance and application of the standard subject to certification and an audit process FDA 21 CFR Part 820 is another example of a Quality Management system While its official designation is a Quality System QS it serves a similar purpose to ISO 13485 Quality management system for medical devices However there is an important distinction 21 CFR Part 820 has a regulatory standing in the United states While many competent authorities require the application of ISO 13485 the framework of ISO 13485 is a standard opposed to a regulation Revised in 2016 ISO 13485 2016 specifies requirements for a quality management system where an organisation needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements The scope of the standard can apply to any organisation or company involved throughout the life cycle of a product including design and or

development production storage and distribution installation or servicing of a medical device and design and development or provision of technical or professional services The 2016 revision is designed to address recent developments in quality management and other updated regulations that relate to the industry Improvements in the new version of the standard include broadening its applicability to include all organisations involved in the life cycle of the product from the concept stage to end of life along with greater alignment with regulatory requirements and post market surveillance including complaint handling Overview of Content Introduction to ISO 13485 Directives and Standards Competent Authorities Notified Bodies How ISO 13485 differs to ISO 9001 ISO TR 14969 Terms Definitions Process Approach Plan Do Check Act PDCA Quality Management System Introduction Regulatory Requirements Risk Based Approach Changes within the QMS Documentation Quality Manual Control of Records Management Responsibility Management Commitment Customer Focus Quality Policy Planning Management Review Resource Management Provision of resources Human resources Infrastructure Work environment contamination control Product realization Planning of Product Realization Design and Development Production and service provision Ctrl of monitoring measuring equipment Measurement Analysis PART 2 Good Documentation Practices Introduction Quality Management Systems PART 3 Validation Introduction Equipment and Software Validation Software Validation Process Validation Packaging Validation      **Guidance on the Relationship Between en ISO 13485** British Standards Institute Staff,1918-03-21 Management Diagnostic equipment medical Quality management Medical equipment Information management      Transition of ISO 13485 Kingster,2019-03 ISO 13485 certification is required by the organization who are dealing with medical devices in any of the stage of its product life cycle It is either required by its customer or the regulatory authorities ISO 13485 released the 3rd revision on March 2016 from ISO 13485 2003 to ISO 13485 2016 and allows three years of transition period ISO 13485 2003 will be withdrawn on February 28th 2019 This book listed the requirements in ISO 13485 2003 and ISO 13485 2016 Both revision of the standards is compared with the difference in the requirements The requirements of ISO 13485 are briefly given in this book The changes of the requirements are discussed extensively      **ISO 13485:2016** ,2017      Medical Devices International Organization for Standardization,2003      **ISO 13485:2016** Internationale Organisation für Normung,2017      **ISO 13485:2016** ,2017      **Medical Devices -- Quality Management Systems -- Requirements for Regulatory Purposes (ISO 13485:2016)** Polska. Polski Komitet Normalizacyjny,2022

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