Module: Classification and Essential Requirements

Level	Master	**Short Name**	CER
Responsible Lecturers	Spitzenberger, Folker, Prof. Dr.		
Department, Facility	Applied Natural Sciences		
Course of Studies	Regulatory Affairs, Master		
Compulsory/elective	Compulsory	**ECTS Credit Points**	5
Semester of Studies	1	**Semester Hours per Week**	4
Length (semesters)	1	**Workload (hours)**	150
Frequency	WiSe	**Presence Hours**	
Teaching Language	English	**Self-Study Hours**	150

The following section is filled only if there is **exactly one** module-concluding exam.

Exam Type	Portfolio Exam	**Exam Language**	English
Exam Length (minutes)		**Exam Grading System**	One-third Grades

Learning Outcomes

The student possesses an in-depth understanding of the fundamental terms and concepts regarding medical device regulation in the EU and Germany. Furthermore, the student is able to place these regulatory requirements within the context of international recommendations based on the guidelines of the International Medical Device Regulators Forum (IMDRF) and its predecessor organization, the Global Harmonisation Task Force (GHTF). This includes detailed knowledge of

• the legal definition of medical devices, including in vitro diagnostic medical devices (IVDs);

• product qualification, specifically the distinction between medical devices and other product groups such as medicinal products, blood products, food and feed, cosmetic products, and consumer goods;

• the risk-based concept for the classification and categorization of medical devices—including combination products and IVDs—under the previous European Directives (90/385/EEC, 93/42/EEC, 98/79/EC), the EU Regulations on medical devices and IVDs (Regulation (EU) 2017/745 and Regulation (EU) 2017/746), and international recommendations (IMDRF/GHTF);

• classification rules under the European Directives and EU Regulations, as well as international recommendations (IMDRF/GHTF);

• essential requirements for medical devices (Annex I of Directives 90/385/EEC and 93/42/EEC) and IVDs (Annex I of Directive 98/79/EC), including requirements for product labeling and product information;

• general safety and performance requirements (Annex I of Regulation (EU) 2017/745 and Annex I of Regulation (EU) 2017/746), including requirements for product labeling and product information;

	• the so-called “Essential principles for safety and performance” in accordance with IMDRF/GHTF recommendations; • any applicable additional German provisions (MPG, MPDG, and subordinate ordinances); • the procedures required to compile technical documentation for medical devices and IVDs regarding compliance with essential requirements or general safety and performance requirements. Based on the intended purpose of medical devices, the student is able to independently determine the regulatory classification of a product. The student is able to identify all relevant regulatory requirements in Germany and the EU for the medical devices in question—including IVDs, software, and combination products—and, on this basis, develop and present a regulatory strategy for the market entry of a medical device or IVD. This applies to all classes and categories of medical devices and IVDs. Furthermore, the student is able to distinguish in detail between the essential requirements set out in Annex I of the European directives, the requirements regarding the performance and safety of medical devices and IVDs set out in Annex I of the European regulations, and the "Essential principles for safety and performance" (based on IMDRF/GHTF recommendations); to apply these to specific cases; and, on this basis, to determine and evaluate the key contents of the technical documentation. In this context, the student is specifically qualified to describe the risk management process—in accordance with Annex I of the EU regulations on medical devices or in vitro diagnostic medical devices (IVDs) and the EN ISO 14971 standard—as an iterative process, and to evaluate it within the framework of an integrated approach within a medical device manufacturer's quality management system.
Participation Prerequisites	

The previous section is filled only if there is **exactly one** module-concluding exam.

Consideration of Gender and Diversity Issues	✔ Use of gender-neutral language (THL standard) ✔ Target group specific adjustment of didactic methods ✔ Making subject diversity visible (female researchers, cultures etc.)
Applicability	
Remarks	

TECHNISCHE HOCHSCHULE LÜBECK

Module Course: Classification and Essential Requirements

(of Module: Classification and Essential Requirements)

Course Type	Online Course	**Form of Learning**	Online supported
Mandatory Attendance	no	**ECTS Credit Points**	5
Participation Limit		**Semester Hours per Week**	4
Group Size		**Workload (hours)**	150
Teaching Language	English	**Presence Hours**	0
Study Achievements ("Studienleistung", SL)		**Self-Study Hours**	150
SL Length (minutes)		**SL Grading System**	

The following section is filled only if there is a course-specific exam.

Exam Type		**Exam Language**	
Exam Length (minutes)		**Exam Grading System**	
Learning Outcomes			
Participation Prerequisites			

The previous section is filled only if there is a course-specific exam.

Contents	Basic definitions within the European and national regulatory systems for medical devices and according to IMDRF/GHTF recommendations Product demarcation/qualification Classification concepts and rules General requirements and principles regarding the safety and performance of medical devices, including IVDs Risk management system and process EN ISO 14971 Product labeling and information
Literature	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, and repealing Council Directives 90/385/EEC and 93/42/EEC Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)

	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices Medical Devices Act in the version of the notification of 7 August 2002 (Federal Law Gazette I, p. 3146), as last amended by Article 223 of the Regulation of 19 June 2020 (Federal Law Gazette I, p. 1328) Medical Devices Law Implementation Act of 28 April 2020 (Federal Law Gazette I, p. 960), as amended from time to time EN ISO 14971 – Medical devices – Application of risk management to medical devices (ISO 14971:2019); All relevant MDCG, MEDDEV, NBOG, IMDRF, and GHTF documents regarding the definition, classification, and general requirements for medical devices (including IVDs) in their currently valid versions Applicable guidance documents from associations such as MedTech Europe, COCIR, BVMed, VDGH, etc.
Remarks	