TECHNISCHE HOCHSCHULE LÜBECK

Module: CE Marking and Certification

Level	Master	**Short Name**	CEM
Responsible Lecturers	Spitzenberger, Folker, Prof. Dr.; Urban, Max, Prof. Dr		
Department, Facility	Applied Natural Sciences		
Course of Studies	Regulatory Affairs, Master		
Compulsory/elective	Compulsory	**ECTS Credit Points**	5
Semester of Studies	2	**Semester Hours per Week**	4
Length (semesters)	1	**Workload (hours)**	150
Frequency	SuSe	**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	1. Graduates of this module are capable of independently—or under the coordination of a scientific team—developing and implementing a regulatory strategy for the selection and execution of appropriate conformity assessment procedures for medical devices, including IVDs. 2. In doing so, graduates of this module distinguish between the tasks and responsibilities of all involved parties—both on the part of the manufacturer and on the part of third parties, such as Notified Bodies and, where applicable, regulatory authorities or expert groups to be involved (e.g., consultation procedures, "scrutiny" procedures pursuant to EU regulations on medical devices or IVDs, etc.). 3. Graduates identify, distinguish, and evaluate all statutory and normative requirements regarding quality and risk management systems within the context of medical device manufacturing (including IVDs). Students possess the competence to independently implement these requirements as part of the establishment, maintenance, and continuous improvement of the management system, specifically as an integrated management system. 4. Students possess a comprehensive overview of the workflow involved in certification and accreditation procedures and are capable of distinguishing between the specific objectives of these procedures. 5. In addition to aspects of conformity assessment focused purely on medical device law, students gain an overview of other legal provisions applicable to the medical device sector—such as those pertaining to artificial intelligence, the benefit assessment (health technology assessment/HTA) of medical devices, and German and European patent law.

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	

Module Course: CE Marking and Certification

(of Module: CE Marking and Certification)

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	Conformity Assessment Procedures for Medical Devices of All Risk Classes, Including in Vitro Diagnostic Medical Devices Consultation Procedures EU Reference Laboratories Common Specifications Modular System for Conducting Conformity Assessment Procedures Quality and Risk Management Systems Integrated Management Systems German and European Patent Law Health Technology Assessment: Reimbursement of health products in Germany and in the European Union Further regulations that can be applicable to (IVD) medical devices, such as, for example, requirements related to artificial intelligence in healthcare
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, as promulgated on 7 August 2002 (BGBl. I p. 3146), last amended by Article 223 of the Ordinance of 19 June 2020 (BGBl. I p. 1328) Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) Medical Devices Law Implementation Act of 28 April 2020 (BGBl. I p. 960), last amended by Article 2 of the Act of 12 May 2021 (BGBl. I p. 1087) DIN EN ISO 14971 – Medical devices – Application of risk management to medical devices (ISO 14971:2019); German version EN ISO 14971:2019 DIN EN ISO 13485 – Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016); German version EN ISO 13485:2016, Corrigendum to DIN EN ISO 13485:2016-08; German version EN ISO 13485:2016/AC:2016 DIN EN ISO/IEC 17000 – Conformity assessment – Vocabulary and general principles (ISO/IEC 17000:2020); Trilingual version EN ISO/IEC 17000:2020 DIN EN ISO/IEC 17021-1 – Conformity assessment – Requirements for bodies providing audit and certification of management systems – Part 1: Requirements (ISO/IEC 17021-1:2015); German and English version EN ISO/IEC 17021-1:2015 DIN EN ISO/IEC 17025 – General requirements for the competence of testing and calibration laboratories (ISO/IEC 17025:2017); German and English versions of EN ISO/IEC 17025:2017 DIN EN ISO/IEC 17011 – Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies (ISO/IEC 17011:2017); German and English versions of EN ISO/IEC 17011:2017 All relevant MDCG, MEDDEV, NBOG, EMA, Team-NB, IMDRF, and GHTF documents relating to conformity assessment procedures and the essential requirements for medical devices (including IVDs), in their currently valid versions Applicable guidance documents from associations such as MedTech Europe, COCIR, BVMed, VDGH, and others
Remarks	