

DRESDEN INTERNATIONAL UNIVERSITY

Study regulations for the Master's Degree Program in "AI, Regulatory Affairs and Transformation in Medical Technology"

Following § 35, section 1 of the law of universities in the Free State of Saxony (Saxon Higher Education Act - SachsHSG) in the version published on May 31, 2023 the Dresden International University (DIU) issues the following examination regulations.

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Appendix 1: Module Descriptions

§ 1 Scope

- (1) These study regulations govern the objectives, content, and structure of the continuing education master's program in "AI, Regulatory Affairs and Transformation in Medical Technology" at Dresden International University based on the Saxon Higher Education Act and the examination regulations.

§ 2 Study Goal

- (1) The master's program in "AI, Regulatory Affairs and Transformation in Medical Technology" The objective of the master's program is to enable students from the target group of specialists and managers to become leaders in healthcare digital transformation and in AI and digital medical product innovation. The design and content of this Master of Business Administration reflects the increasing use of digital and AI processes in medical technologies and the critical role these technologies are growing to have in the development and approval of processes of even non-digital medical devices and medical products. A core concept of the Master of Business Administration is that digital health and AI are fundamentally important to future healthcare delivery and that the following three principles are essential for leaders and all mutually intertwined: (i) understanding of healthcare practice and its current digitalization and potential digital transformation; (ii) understanding of digital/AI medical product development practices and their current digitalization and potential digital transformation; (ii) understanding of the medical technology and medical device quality and regulatory processes, across the total life cycle and for developers and for care systems.
- (2) The master's program and the master's thesis that concludes it are particularly practice-oriented and are intended to significantly advance the integration of university teaching/research with practical concerns.

§ 3 Structure of the Program, Language of Instruction

- (1) The program has a modular structure and is divided into two parts:

The program has a modular structure and is divided into two parts: The first part of the master's program consists of classroom-based courses and self-study phases in nine modules. The first part of the master's program comprises 378 classroom hours spread over three semesters. Together with self-study, a total of 45 credit points must be earned.

The second part of the master's program consists of writing and defending (colloquium) the master's thesis in the fourth semester. A total of 15 credit points must be earned.
- (2) The courses are usually conducted in a coordinated complex of lectures, seminars and practical workshops.
- (3) The courses are usually offered in English.
- (4) The content and qualification objectives, teaching and learning methods, prerequisites, applicability, frequency, workload, and duration of the individual modules can be found in the module descriptions (Appendix 1).

§ 4

Credit Points, ECTS Grades, and German Grades

- (1) Successful academic progress is documented by the awarding of credit points. Credit points are awarded upon passing the master's examination or module examination. The total workload (classroom and self-study) is assumed to be 25 hours per credit point. This corresponds to an average of 15 credit points per semester (part-time).
- (2) The module descriptions specify how many credit points can be earned for each module. Credit points are earned when the module examination for the corresponding module has been passed.
- (3) In addition to the German grade on a scale of 1 to 5, students are also given a grade table with their overall grade, which allows them to see how their performance ranks relative to the final results in the degree program and thus facilitates the transfer of their grade in recognition procedures.
- (4) Grade tables are issued once the cumulative number of graduates reaches 100.

§ 5

Study Schedule

The study schedule for the modules of the master's program comprises courses totaling 900 attendance hours (AH). One AH corresponds to 60 minutes of teaching. One double lesson (DL) corresponds to 90 minutes of teaching.

The following table shows the distribution of AH and the ECTS credits that can be achieved, taking into account the portion of self study (SS), distributed across the semesters and modules:

Module	1. Semester			2. Semester			3. Semester			4. Semester		
	ECTS	AH	SS	ECTS	AH	SS	ECTS	AH	SS	ECTS	AH	SS
REGU/M000 Fundamentals of scientific working	5	42	83									
REGU/M010 New skill sets for leadership in digital healthcare delivery and digital medical product development	5	42	83									
REGU/M020 Current models of technology in healthcare delivery	5	42	83									
REGU/M030 Current models of medical technology development				5	42	83						
REGU/M040 Current medical device regulatory processes				5	42	83						
REGU/M050 Managing digital and AI-enabled transformation in healthcare delivery				5	42	83						
REGU/M060 Managing digital and AI-enabled transformation of medical technology development							5	42	83			
REGU/M070 Managing digital and AI-enabled transformation of medical device regulatory processes							5	42	83			
REGU/M080 Technology competencies for leaders in future healthcare							5	42	83			
REGU/MA Master's Thesis										15	0	375
Hours per semester	15	126	249	15	126	249	15	126	249	15	0	375
Hours in total		375			375			375			375	

The total number of credits to be earned during the program, including the master's thesis, is 60 credits.

§ 6

Study Advisory Service

Dresden International University (DIU) ensures that students have sufficient opportunity to seek advice on study-related matters.

§ 7
Implementation of the Regulation and Publication

These study regulations shall enter into force on October 1, 2026, and shall be published in an appropriate form.

Dresden, 29/01/2026

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