

DRESDEN INTERNATIONAL UNIVERSITY

Examination 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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§ 1 University Degree

The continuing education master's program in "AI, Regulatory Affairs and Transformation in Medical Technology" concludes with a master's examination as a professionally qualifying degree in accordance with § 39 (1) SachsHSG (without reference to research activities). Upon successful completion of the master's examination, the academic degree "Master of Business Administration" is awarded.

§ 2

Standard Period of Study

- (1) The master's program is usually completed on a part-time basis alongside work, with phases of classroom-based and supported self-study. The standard period of study comprises the coursework, the examinations, including the master's thesis, and all required academic achievements. It lasts four semesters. The study regulations and the range of courses offered ensure that preliminary examination requirements and examinations can be completed within the specified time periods. In order to enable students to take advantage of the statutory maternity leave periods and parental leave periods, the duration of the program is regulated individually at the student's request. Periods of maternity leave and parental leave are not counted toward the current deadlines. Similar regulations apply to disabled and chronically ill students.

§ 3

Admission Requirements

- (1) Admission to higher education is governed by the provisions of § 18 SächsHSG. Applicants must submit written application documents to the DIU.
- (2) Admission to the master's program is open to anyone who
 - already possesses a college or university degree (equivalent to 240 credit points) recognised in the country of origin AND
 - can demonstrate at least one year of professional experience in industry AND
 - experiences in AI and digital products or processes and digitalization AND
 - have advanced knowledge of English on the TOEFL level 570, iBT79 or IELTS 6.0 or similar knowledge.
- (3) Applicants with less than 210 credit points can, among other things, acquire missing credit points by successfully participating in the additional modules (AddM) "Practical Semester" and "Module Analysis" provided for this purpose. The study period is extended accordingly for these applicants.
- (4) Applicants are generally selected on the basis of a formal individual assessment of their eligibility in accordance with §3 (2) of the examination regulations. If necessary, an admission interview may also be conducted by the scientific director of the master's program. During the admission interview, applicants can demonstrate their personal suitability and motivation for the program. The requirement for an admission interview may be waived, in particular if the written documents clearly demonstrate personal suitability and motivation or the lack thereof.
- (5) The central admissions office of the DIU, which is part of the DIU's study affairs department, decides whether the admission requirements mentioned in paragraph 2 have been met. If there are a limited number of places available, the scientific director of the master's program and the DIU admissions office will select from among the applicants who formally meet the admission requirements. The selection is based on the applicants' previous achievements and the assessment of their personal suitability and motivation during the admission interview.
- (6) As a result of the admission review, applicants will be notified within two weeks whether they have been admitted to the master's program. If admission is denied, the application may be resubmitted once.

- (7) Applicants are expressly informed that the profession must always be practiced in accordance with the provisions of the currently valid legal regulations.

§ 4

Admission Interview

- (1) The purpose of the admission interview is to assess and evaluate the professional and personal suitability as well as the motivation of the applicants as a prerequisite for successful participation in the master's program. The admission interview is not part of the formal admission requirements according to §3 and is only conducted if necessary and/or if there are a limited number of places available.
- (2) The admission interview should not last longer than 30 minutes. Applicants will be invited by the scientific director of the master's program.
- (3) Following the admission interview, applicants will be notified within two weeks whether they have been admitted to the master's program.

§ 5

Master's Thesis; Structure and Deadlines

- (1) The master's examination can be taken by anyone who is enrolled in the master's program "AI, Regulatory Affairs and Transformation in Medical Technology" at Dresden International University.
- (2) The master's examination is divided into two parts.

The first part of the master's examination consists of examinations on the various modules (module examinations) of the program and comprises a total of 45 credit points.

The second part involves writing a master's thesis and defending it (colloquium). A total of 15 credit points can be earned in this second part.
- (3) The second part of the master's examination begins with the registration of the master's thesis (cf. §12 (2)).
- (4) In order to take examinations, students must register in the form specified by the DIU. Students will be notified of the registration deadlines. This does not exempt candidates from the deadlines for taking the master's examination in accordance with paragraph 6.
- (5) Admission to an examination may only be refused if
 1. the requirements specified in paragraphs 1 or 4 are not met, or
 2. the documents are incomplete, or
 3. the candidate has definitively failed the final examination in the same or, in accordance with state law, a related degree program, or is currently undergoing an examination procedure, or
 4. the candidate has definitively failed the examination by exceeding the deadlines for registering for the examination or taking it, or
 5. the candidate has lost their right to take the examination in accordance with state law by exceeding the deadlines for registering for or taking the respective examination.
- (6) The master's examination must be taken by the end of the standard period of study. If the master's examination has not been taken within four semesters after the end of the standard period of study, it is considered failed for the first time. A failed master's examination can only be repeated once within one year. Admission to a second repeat examination is only possible upon application for the next possible examination date. A

further repeat examination is not permitted. After this period has expired, it is considered failed.

§ 6

Module Examinations

- (1) Module examinations consist of one or, in justified exceptional cases, several examination performances in a module. The number of credit points to be earned for each module can be found in the appendix to the study regulations.
- (2) The examination components are completed during the course of study. The dates of the examinations are usually announced at the beginning of the semester's courses, but no later than four weeks before the examination date.

§ 7

Types of Examinations

- (1) Examination components are oral/practical examination components in accordance with § 36 (7) SächsHSG (oral/practical examinations, tests, presentations, lectures), written examinations, and other written work (assignments, case studies, project reports).
- (2) Oral/practical examinations are intended to demonstrate that the candidate is able to present the subject matter of the examination, classify specific questions within this context, and present methodological approaches to solving relevant problems.
- (3) Within the scope of the oral/practical examination, written assignments may also be required to an appropriate extent, provided that this does not detract from the oral nature of the examination. In addition, limited topics specified by the candidate may be examined, giving the candidate the opportunity to express themselves coherently on such topics.
- (4) Oral/practical examinations are conducted with at least one examiner and one assessor in group or individual examinations. If necessary, the assessor may also be replaced by a video recording. They should last at least 20 minutes per candidate in individual and group examinations.
- (5) The main subjects and results of the oral/practical examination must be recorded in a protocol. The candidate must be informed of the result of the examination within two weeks of the oral/practical examination.
- (6) Through written examinations and other written examination papers, the candidate should demonstrate that they can document their knowledge in a limited time and with limited resources, identify problems using the common methods of the subject studied, find ways to solve them, and present these solutions appropriately. Written examinations shall last at least 60 and at most 180 minutes. Exceptions may be permitted. Written examinations and other written tests that must be passed in order to continue or complete the course of study shall be assessed by at least one examiner, or in the case of the final repeat examination, by at least two examiners. If there are several examiners, the grade is calculated as the arithmetic mean of the individual assessments, rounded to the nearest grade level in accordance with § 8 (2). The assessment process should generally be completed within four weeks.
- (7) In the case of written examinations, protocols shall be written, which shall include, in particular, the names of the examiner(s), the invigilators, an attendance list of the candidates, and the examination questions issued.

- (8) If a student can credibly demonstrate that they are unable to take examinations in whole or in part in the prescribed form due to a long-term or permanent physical disability or chronic illness, or due to pregnancy-related restrictions or during maternity or parental leave, the examination board must grant them compensation for disadvantages. Suitable measures for compensating for disadvantages include, for example, extended processing times, breaks during processing, use of other media, use of other examination rooms within the university, or a different examination date. If these measures are unsuitable in individual cases, it is also possible to change the duration, type, or form of the examination. A medical certificate or certificate from a public health officer may be required for this purpose. Any such restriction must be reported to the examination board at least three weeks before the examination date, or immediately after it becomes known.
- (9) If a student can credibly demonstrate that they are unable to complete their examinations as prescribed due to caring for their own children up to the age of fourteen or caring for close relatives, the examination board shall, at the student's request, allow them to complete the examinations in an equivalent manner, including by means of a different type of examination. Such a request must be submitted to the examination board at least three weeks before the examination date, or immediately after the facts become known. Close relatives are children, parents, grandparents, spouses, and partners. The examination board shall decide how the examination is to be taken in consultation with the responsible examiner at its discretion.

§ 8

Assessment of Examination Performance, Formation and Weighting of Grades

- (1) The grades for the module examinations are determined by the respective examiners. The following grades are used to assess examination performance:

1 = very good:	an outstanding performance;
2 = good:	a performance that significantly exceeds average requirements;
3 = satisfactory:	a performance that meets average requirements;
4 = adequate:	performance that still meets the requirements despite its shortcomings;
5 = unsatisfactory:	a performance that no longer meets the requirements due to significant shortcomings.

For a differentiated assessment of examination performance, intermediate values can be formed by lowering or raising the individual grades by 0.3; the grades 0.7, 4.3, 4.7, and 5.3 are excluded.

- (2) If a module examination consists of several examination performances, the module grade is calculated from the average of the weighted grades of the individual examination performances, if applicable. Only the first decimal place after the comma is taken into account; all other places are deleted without rounding. The module grade is
- | | |
|--|-----------------|
| for an average up to and including 1.5: | very good |
| for an average of 1.6 to 2.5 inclusive: | good |
| for an average of 2.6 to 3.5 inclusive: | satisfactory |
| with an average of 3.6 to 4.0 inclusive: | sufficient |
| with an average of 4.1 or higher: | unsatisfactory. |
- (3) An overall grade is calculated for the master's examination. The overall grade for the master's examination is calculated as the average of the module grades weighted with the credit points and the grade for the master's thesis weighted with 15 credit points. Paragraph 2 applies accordingly to the calculation of the overall grade.

- (4) The grade for the master's thesis is calculated from the grade for the written thesis with a weighting factor of 2 and the grade for the defense with a weighting factor of 1.
- (5) If the grade for the master's thesis is 1.0 and the overall grade for the master's examination is better than 1.3, the candidate is awarded the overall grade "with distinction."

§ 9

Absence, Withdrawal, Cheating, Breach of Order

- (1) If the candidate misses an examination date that is binding for them without good reason, or if they withdraw from the examination after it has begun without good reason, the examination performance is considered to be graded as "unsatisfactory" (5.0). The same applies if a written examination is not completed within the specified time limit.
- (2) The reason given for the withdrawal or absence must be reported to the examination board in writing without delay and must be substantiated. In the event of illness of the candidate or a child for whom he or she is primarily responsible or a relative in need of care, a medical certificate, or in cases of doubt a certificate from a public health officer, must be submitted. If the reason is accepted, a new date will be set. In this case, the examination results already available will be taken into account.
- (3) If the candidate attempts to influence the result of the examination by deception or the use of unauthorized aids, the examination in question shall be graded as "unsatisfactory" (5.0). Possession of unauthorized aids after the examination tasks have been handed out or after the oral examination has begun is equivalent to the use of unauthorized aids, unless the examination participant can prove that the possession was neither intentional nor negligent.
- (4) A candidate who disrupts the proper conduct of the examination may be excluded from continuing the examination by the respective examiner or supervisor; in this case, the examination in question shall be graded as "unsatisfactory" (5.0). In serious cases, the examination board may exclude the candidate from taking further examinations.
- (5) The candidate may, within two weeks, submit a written request stating the reasons why the decisions under paragraph 3, sentences 1 and 2, and paragraph 4 should be reviewed by the examination board. Adverse decisions must be communicated to the candidate in writing without delay, stating the reasons and providing information on the right of appeal.

§ 10

Passing, Failing, and Repeating Module Examinations

- (1) A module examination is passed if it has been graded at least "sufficient" (4.0). In this case, credit points are awarded. If a module examination consists of several examination components, an examination component graded as "unsatisfactory" can be compensated for by a better-graded examination component if the grade formed in accordance with § 8 (2) is at least "sufficient" (4.0) overall. Notwithstanding this, it may be stipulated that a module examination with several examination components is only passed if certain examination components have been graded at least "sufficient" (4.0).
- (2) Failed module examinations may be retaken within one year. The period begins with the announcement of the initial failure of the module examination. After this period has expired, they are again considered failed. Only those examination performances that were not graded at least "sufficient" (4.0) must be retaken. Repeating a passed examination is not permitted. Failed attempts at other universities and equivalent institutions of higher education in the Federal Republic of Germany must be taken into account.

- (3) Admission to a second repeat examination is only possible upon application for the next possible examination date. The application must be submitted in writing to the examination board within four weeks of receiving notification of failure of the first repeat examination. A further repeat examination is not permitted.

§ 11

Recognition of Academic and Examination Achievements, Periods of Study, and Crediting of Achievements obtained outside a University

- (1) The competent examination board shall decide on the recognition of study and examination achievements or the crediting of skills acquired outside the university upon application by the student. The decision on crediting or recognition shall be made on the basis of appropriate information about the qualifications for which crediting or recognition is sought. The responsibility for providing sufficient information lies primarily with the applicant. The burden of proof that an application does not meet the relevant requirements lies with the examination board. If credit transfer or recognition is refused or no decision is made, legal remedies may be sought.
- (2) Academic and examination achievements in the same or a related degree program at a university or equivalent institution of higher education in the Federal Republic of Germany or in the European Higher Education Area are recognized without a special equivalence assessment.
- (3) Study and examination achievements in another degree program are recognized provided that there are no significant differences in terms of the skills acquired. In this context, an overall assessment must be made with regard to the purpose of recognition. Recognition includes an examination of the level, scope, quality, profile, and learning outcomes. If there is a significant difference, this must be substantiated by the university.
- (4) Paragraphs 1, 2, and 3 apply accordingly to periods of study, academic achievements, and examinations in state-recognized distance learning programs and at dual universities; paragraph 3 also applies to periods of study, academic achievements, and examinations at technical and engineering colleges and officer training colleges in the former GDR.
- (5) Knowledge, skills, and competencies acquired outside the higher education system may be credited in accordance with § 1, provided that they are sufficiently documented and are equivalent in content and level to the competency objectives of the study modules to which they are to be credited. Furthermore, the requirements for admission to higher education must be met at the time of crediting.
- (6) On the basis of quality-assured equivalence assessments, it is also possible to transfer credits for continuing education and training qualifications on a flat-rate basis.
- (7) Knowledge, skills, and competencies acquired outside the higher education system can be credited for up to 50 percent of the credit points to be acquired.
- (8) If study and examination achievements are recognized or competencies acquired outside of higher education are credited, the grades—insofar as the grading systems are comparable—must be adopted and included in the calculation of the overall grade. In the case of incomparable grading systems, the notation "passed" is included. It is permissible to indicate the recognition or crediting in the transcript.

§ 12 Master's Thesis

- (1) The master's thesis, which consists of the written thesis and its defense (colloquium), is an examination that concludes the academic training. The master's thesis should demonstrate that the candidate is able to work independently on a problem from their field within a specified period of time, applying scientific methods and presenting their work in a linguistically correct manner.
- (2) It is possible to begin work on the master's thesis, subject to § 10, if at least 32 of the total 45 required credit points have been earned in the compulsory area of the first part of the master's examination (module examinations). Those who have successfully passed the master's thesis are admitted to the defense of the master's thesis.
- (3) The master's thesis is supervised by a university lecturer or another person authorized to conduct examinations under state law or appointed in accordance with § 18 of these examination regulations who is qualified to represent the master's program. If the master's thesis is to be carried out at an institution outside the university, the approval of the chair of the examination board is required.
- (4) Candidates may express their preferences for topics, which require the approval of the scientific director of the master's program. The topic and date must be recorded. The topic may only be returned once and only within two months of being assigned.
- (5) The processing time for the master's thesis is six months. It can be started at the earliest after the requirements according to § 12 (2) have been met. The topic, task, and scope of the master's thesis must be designed in such a way that the deadline for processing can be met. The examination board may extend the processing time by a maximum of two months upon justified request. Exceptions may be granted in individual cases.
- (6) The written master's thesis must be submitted to the DIU in duplicate in written and digital form by the deadline; the date of submission must be recorded. The author must declare in writing that they have written the thesis independently and have not used any sources or aids other than those specified. In the event of deception, the master's thesis will be graded as "unsatisfactory" (5.0).
- (7) The master's thesis must be written in English. Submission in German must be requested by the candidate and agreed separately after approval by the examination board.
- (8) The written master's thesis is usually assessed independently by two examiners. One of the examiners should be the supervisor of the thesis, taking into account § 18 (1). Each examiner shall evaluate the thesis in a written report, stating the grade. This grade is an examination result and is determined in accordance with § 8 (1). In the event of a discrepancy between the two evaluations, the grade shall be determined by calculating the arithmetic mean.
- (9) The assessment process should not exceed eight weeks. If one examiner grades the thesis as "unsatisfactory" (5.0) or if the examiners' grades differ by more than one grade, the examination board shall decide on the final grade. A third examiner may be consulted in this case.
- (10) The defense of the master's thesis is an examination and is assessed in accordance with § 8 (1). The grade for the master's thesis is determined in accordance with § 8 (4).
- (11) The master's thesis can only be repeated once if the overall assessment of the master's thesis is lower than "sufficient" (4.0). However, the new topic of the master's thesis may

only be resubmitted within the period specified in paragraph 4 if the candidate did not make use of this option when writing their first master's thesis.

- (12) The candidate must explain the subject matter and results of their master's thesis in a colloquium. Only those who have earned 45 credit points in the first part of the master's examination and who have achieved an overall grade of no less than "sufficient" (4.0) in the written master's thesis will be admitted to the colloquium. The colloquium usually takes place within four weeks after the assessments before the examiners of the thesis, who are usually the two examiners in accordance with § 12 (8). Section 8 (1) applies to the assessment of the colloquium. The grade is announced to the candidate after the colloquium. If the overall performance in the colloquium is assessed as "unsatisfactory," the colloquium may be repeated once within a period of eight weeks. The minutes must be signed by the examiners and the assessor.
- (13) Section 9 (1) applies accordingly to failure to attend the colloquium.
- (14) A second repetition of the written master's thesis or the colloquium and the repetition of a passed master's thesis or a passed colloquium are excluded.
- (15) The DIU has published detailed information on the procedure and form of the master's thesis in an organizational instruction.

§ 13

Overall Grade

- (1) The master's examination is passed if the academic achievements required in accordance with § 5 (3) have been completed, the corresponding examinations have been passed, and the master's thesis has been graded at least "sufficient" (4.0).
- (2) Section 8 (2) applies accordingly to the designation of the overall grade. The grade is shown in the certificate as a numerical value with one decimal place and the verbal designation of the grade is added in brackets.
- (3) If the examination candidate has not passed the master's examination, a certificate will be issued upon request and upon presentation of the relevant evidence and the certificate of exmatriculation, which contains the examination achievements and their grades as well as the examination achievements still missing and indicates that the master's examination has not been passed.

§ 14

Certificate and Master's Degree Certificate

- (1) The examination candidate will receive a certificate of the master's examination passed without delay, usually within four weeks. The certificate documents the results of the module examinations, the topic, supervisor, and grade of the master's thesis, as well as the overall grade including all credits earned. The transcript bears the date of the last examination and is signed by the chair of the examination board and stamped with the seal of Dresden International University. All examinations, including additional ones, are listed in an appendix to the transcript.
- (2) At the same time as the certificate, the examination candidate receives the diploma from Dresden International University. With the presentation of this diploma, Dresden International University awards the academic degree "Master of Business Administration" The diploma bears the date of the certificate.

- (3) Dresden International University issues a Diploma Supplement (DS) in accordance with the "Diploma Supplement Model" of the European Union/Council of Europe/UNESCO. In addition to the Diploma Supplement, Dresden International University will, upon request, provide the examination candidate with translations of the certificate of academic degree and the transcript in English.

§ 15

Invalidity of the Master's Examination

- (1) If the candidate has cheated in an examination and this fact only becomes known after the certificate has been issued, the grade for the examination may be corrected in accordance with § 9 (3). If necessary, the module examination(s) and the master's examination may be declared "failed."
- (2) If the requirements for taking an examination were not met without the examination candidate intending to cheat, and this fact only becomes known after the certificate has been issued, this deficiency shall be remedied by passing the examination. If the examination candidate deliberately obtained permission to take the examination by false pretences, the examination may be declared "unsatisfactory" and the master's examination "failed".
- (3) The examination candidate shall be given the opportunity to comment before a decision is made.
- (4) The incorrect certificate shall be withdrawn by the DIU and, if necessary, a new one shall be issued. If the master's examination has been declared "failed" due to deception, the incorrect certificate, the translations of the certificate and the diploma, and the diploma supplement shall also be withdrawn. Decisions based on paragraphs 1 and 2 may only be made within five years of the date of the certificate.

§ 16

Inspection of Examination Files

Within one year of completion of the examination procedure, the examination candidate shall be granted access to his or her written examination papers, the reports on the written master's thesis, and the examination records upon request.

§ 17

Examination Board

An examination board shall be formed to organize the master's examination and perform the tasks assigned by these examination regulations. The examination board shall monitor the degree program and shall only intervene if the examination regulations are violated or if its intervention is mandatory under the examination regulations. It shall consist of at least three members, namely the members of the Academic Management, a representative of the DIU's university management, and a person authorized to conduct examinations under state law in accordance with § 36 (6) SächsHSG. The term of office of the members of the examination board shall generally be three years.

- (1) The Examination Board may temporarily call upon lecturers authorized to conduct examinations for the degree program to assist in its decision-making. These persons have advisory votes.

- (2) The chairperson and the other members of the examination board are appointed by the president of Dresden International University. The chairperson usually manages the affairs of the examination board.
- (3) The examination board ensures that the provisions of the examination regulations are complied with. The examination board makes suggestions for qualitative improvements to the study regulations, the study schedule, and the examination regulations.
- (4) The members of the examination board have the right to attend the examination.
- (5) The members of the examination board are bound to secrecy regarding the subjects of their activities.

§ 18

Examiners and Assessors

- (1) The examination board of the master's program appoints the examiners and assessors. Only university lecturers and other persons authorized to conduct examinations under state law may be appointed as examiners. Unless there are compelling reasons for deviation, they must be independently teaching the subject area to which the examination relates at a university. If necessary, persons who are authorized to teach independently only in a subfield of the examination subject may also be appointed as examiners. As a rule, only persons who have passed the university degree examination or a comparable examination in the same subject may be appointed as assessors. Exceptions to this rule may be permitted if justified.
- (2) The names of the examiners must be communicated to the candidate by the examination board in good time.
- (3) Section 17 (5) applies accordingly to examiners and assessors.

§ 19

Entry into force and publication

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

Dresden, 29/01/2026

Prof. Dr. Antonio Hurtado

P r o f . D r . A n t o n i o H u r t a d o (Jan 29, 2026 15:05:34 GMT+1)

Prof. Dr.-Ing. habil. Antonio Hurtado

President of DIU Dresden International University

Prüfungsordnung M-REGU

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