60. DESIGN AND CERTIFICATION OF MEDICAL DEVICES[i]	
Level II	
Department of Information Engineering (DINFO)	
Course coordinator	Leonardo Bocchi
Executive Committee	Leonardo Bocchi Antonio Lanatà Tommaso Pecorella
Practical-professional profile of the course and industry sector of reference	The Level II Master course in Design and Certification of Medical Devices trains professionals with an in-depth knowledge of the European Directives on Medical Devices and Medical Devices for In Vitro Diagnostics, at the basis of the regulatory and qualitative activity within a company supplying or producing one of these devices, but also at the basis of the work of Entities that have to evaluate them. The course aims to provide the theoretical/practical basis for establishing and updating the technical dossier of a Medical Device or In Vitro Diagnostic Medical Device so that the learner can follow each stage of the product's life. It will deal with the design, the drafting of technical specifications, and analysis of the processes in which the product will be involved; the transfer to production and the branching out of traceability activities for the product and its components; and the life of the product after delivery to the customer with performance analysis and vigilance over complaints and problems that may arise. The Master Course also aims to provide students with the theoretical/practical means of assessing the conformity of a product concerning the relevant European Directives, developing in students the concept of attention to compliance with the requirements dictated by the European Directives. The course trains professionals who can make use of the knowledge acquired at companies producing and/or supplying Medical Devices and Medical Devices for In Vitro Diagnostics in the regulatory, qualitative, and design fields or at Notified Bodies (Certification Bodies or testing laboratories), to assess the conformity of products to European Directives.
Access prerequisites	Master's degree obtained following the regulations under Ministerial Decree No. 270/2004 or Master's degree under Ministerial Decree No. 509/1999 in one of the following classes: • LM-8 Industrial Biotechnology • LM-9 Medical, Veterinary, and Pharmaceutical Biotechnology; • LM-17 Physics; • LM-18 Computer Science; • LM-21 Biomedical Engineering; • LM-22 Chemical Engineering • LM-23 Civil Engineering • LM-24 Building Systems Engineering • LM-32 Computer Engineering; • LM-33 Mechanical Engineering; • LM-34 Naval Engineering • LM-35 Environmental and Land Use Engineering • LM-40 Mathematics; • LM-77 Economic and Business Sciences Single-cycle degree obtained according to the system under Ministerial Decree

	No. 270/2004 (or specialist degree under Ministerial Decree No. 509/1999 equated under I.D. July 9, 2009) in one of the following classes: • LM-13 Pharmacy and Industrial Pharmacy • LM-41 Medicine and Surgery • LM-42 Veterinary Medicine • LMG/01 Law Degree awarded according to a system prior to Ministerial Decree No. 509/1999 in • Biotechnologies • Pharmaceutical chemistry and technologies • Economics • Pharmacy • Physics • Law • Engineering • Medicine and Surgery • Veterinary medicine Degree awarded according to a system prior to Ministerial Decree No. 509/1999 of closely related content, deemed suitable by the Executive Committee or a Commission specifically appointed by it.
Admission procedure	Selection by academic qualifications
Duration	12 months
Teaching methods	Blended
Language of instruction	Italian
Attendance requirements	67%
Location of the course	School of Engineering, Department of Information Engineering, Via S. Marta n. 3, 50139 Florence (FI)
Foreseen lecture schedule	On the weekend, Friday and Saturday.
Examinations procedures and schedule	There will be tests, mainly by oral examination, at the end of each module.
Final examination	The final examination consists of the presentation of a paper concerning one or more of the course topics, preferably explored in depth during the internship or other hands-on activity.

Available places and enrolment fees	
Full-fee students	
Minimum number	6
Maximum number	25
Enrolment fee	€2,000
Single Modules	
None planned	

Description of the activities and training objectives of the internship	The internship will focus on applying the knowledge covered by the course within the design and marketing flow of an electromedical product, preferably within a company producing this type of system. 450 total hours of internship.

[i] This document is a translation of the form A.1 relating to the characteristics of the course attached to the Decree of the Deputy number 873 (record 158006) of 25th of July 2022, drafted in Italian and issued on the Master | Didattica | Università degli Studi di Firenze | UniFI and which therefore constitutes the only official document. This English translation cannot be used for legal purposes and has the sole purpose of supplying information in English on the content of the public notice.