| **Course Title:** Security, evaluation and economic development of medical devices |
|---|

| **Course description** | |
|---|---|
| Course components | 60 CM |
| European credits | 6 ECTS |
| Master specialization | Ingénierie pour la santé / Mechatronic Systems for Rehabilitation |
| Semester | S3 |

### a) Objective

The objective of this course is to give an overview of the societal and economic constraints of medical devices. It is divided into three parts.The first part examines several central aspects with respect to the safety and the acceptability of assistive and rehabilitation technologies.

The second part presents risk management concepts and techniques for the development of medical robots, more specifically of rehabilitation robots. Study of the economic viability of a project. Medical economic development: study of the various stages of the development of a device with medical use, the proof of concept in the launch on the market.

The last part gives the general principles of clinical research and the statistical basic tools.

### b) Content

Definition and application of basic concepts for risk management: risk, harm, safety, hazard, hazardous situation, safety integrity, safety integrity level, etc.

Risk analysis methods (Fault Tree Analysis, Failure Mode Effects and Criticality Analysis, HAZOP, etc.) based on system modeling. Risk reduction techniques for medical robots (Hardware and software fault avoidance techniques, fault tolerance mechanisms, etc.)

Acceptability and ergonomics of the assistive technologies. Relationship between Assistive Technology and Inclusive Design.

Clinical trials methodology and protocol design.

Data Analysis, Biostatistics

Engineers, designers and technicians collaboration methodology

Evaluation of a medical product

Certification principles and regulations

Life of the product

### c) Pre-requisites

None

### d) Evaluation

Written examinations and practical work evaluation

| **Teaching method** | | | |
|---|---|---|---|
| In class work | Total time | Weekly hours | Enrollment |
| Lectures | 60 h | | |
| Tutorials | | | |
| Practical work | | | |
| Project | | | |
| Other | | | |