

## [GBM203] MEDICAL CERTIFICATIONS AND STANDARDS

### GENERAL INFORMATION

<b>Studies</b>	DEGREE IN BIOMEDICAL ENGINEERING		<b>Subject</b>	?
<b>Semester</b>	2	<b>Course</b>	3	<b>Mention / Field of specialisation</b>
<b>Character</b>	COMPULSORY		<b>Language</b>	CASTELLANO
<b>Plan</b>	2022	<b>Modality</b>	Face-to-face	<b>Total hours</b>
<b>Credits</b>	4,5	<b>Hours/week</b>	4.18	75.3 class hours + 37.2 non-class hours = <b>112.5 total hours</b>

### PROFESSORS

AZPI-FORTEA MENDEZ, EIDER

### REQUIRED PREVIOUS KNOWLEDGE

Subjects	Knowledge
(No specific previous subjects required)	(No previous knowledge required)

### LEARNING RESULTS

LEARNING RESULTS	KC	SK	AB	ECTS
<b>GBR309</b> - To assess regulations, certifications and legal aspects in solving Biomedical Engineering problems		x		3,78
<b>G-RTR1</b> - To develop interdisciplinary projects specific to their specialty and of gradual complexity, - becoming aware of respect for human rights and fundamental rights, and analyzing and assessing the impact of the proposed solutions on the SDGs - to acquire and/or apply basic, advanced and /or avant-garde, demonstrating the ability to work in multidisciplinary teams and/or undertake further studies with a high degree of autonomy		x		0,4
<b>G-RTR2</b> - To express information, ideas and the arguments that support them in an orderly, clear and coherent manner, orally and in writing, based on quality information, self-made or obtained from different sources, using inclusive and non-discriminatory language		x		0,32
<b>Total:</b>				<b>4,5</b>

KC: Knowledge or Content / SK: Skills / AB: Abilities

### SECONDARY LEARNING RESULTS

**RGB390** [!] *Definir y gestionar los objetivos y la planificación de un proyecto que le permita adquirir y/o reforzar los conocimientos de tecnologías específicas de su especialidad,- que en ocasiones llegan a la vanguardia del conocimiento- y definir una estrate*

LEARNING ACTIVITIES	CH	NCH	TH
Carrying out/resolving projects/challenges/cases, etc. to provide solutions to problems in interdisciplinary contexts, real and/or simulated, individually and/or in teams	2,5 h.	1,5 h.	4 h.
EVALUATION SYSTEM	W	MAKE-UP MECHANISMS	
Reports on the completion of exercises, case studies, computer exercises, simulation exercises, laboratory exercises, term projects, challenges and problems	100%	Observation (technical capacity, attitude and participation)	

CH - Class hours: 2,5 h.

NCH - Non-class hours: 1,5 h.

TH - Total hours: 4 h.

**RGB391** [!] *Coordinar el equipo de trabajo, estimulando la cohesión y buen clima para lograr la integración de todas las personas y su contribución para alcanzar un rendimiento apropiado, tanto a nivel individual como grupal, para el desarrollo del proyecto en*

LEARNING ACTIVITIES	CH	NCH	TH
Carrying out/resolving projects/challenges/cases, etc. to provide solutions to problems in interdisciplinary contexts, real and/or simulated, individually and/or in teams	1,9 h.	1,1 h.	3 h.
EVALUATION SYSTEM	W	MAKE-UP MECHANISMS	
Self-assessment	25%	Observation (technical capacity, attitude and participation)	
Co-assessment	25%		

Observation (technical capacity, attitude and participation) 50%

**CH - Class hours:** 1,9 h.

**NCH - Non-class hours:** 1,1 h.

**TH - Total hours:** 3 h.

**RGB392** [!] *Identificar y argumentar de forma precisa los ODS en los que incide el proyecto realizado, aportando posibles acciones para la mejora.*

**LEARNING ACTIVITIES**

	<i>CH</i>	<i>NCH</i>	<i>TH</i>
Carrying out/resolving projects/challenges/cases, etc. to provide solutions to problems in interdisciplinary contexts, real and/or simulated, individually and/or in teams	1,9 h.	1,1 h.	3 h.

**EVALUATION SYSTEM**

Reports on the completion of exercises, case studies, computer exercises, simulation exercises, laboratory exercises, term projects, challenges and problems

*W*

100%

**MAKE-UP MECHANISMS**

Observation (technical capacity, attitude and participation)

**CH - Class hours:** 1,9 h.

**NCH - Non-class hours:** 1,1 h.

**TH - Total hours:** 3 h.

**RGB393** [!] *Elabora la memoria del proyecto, aportando argumentos elaborados y haciendo un uso correcto, inclusivo y no discriminatorio del lenguaje.*

**LEARNING ACTIVITIES**

	<i>CH</i>	<i>NCH</i>	<i>TH</i>
Carrying out/resolving projects/challenges/cases, etc. to provide solutions to problems in interdisciplinary contexts, real and/or simulated, individually and/or in teams	2,5 h.	1,5 h.	4 h.

**EVALUATION SYSTEM**

Reports on the completion of exercises, case studies, computer exercises, simulation exercises, laboratory exercises, term projects, challenges and problems

*W*

100%

**MAKE-UP MECHANISMS**

Observation (technical capacity, attitude and participation)

**CH - Class hours:** 2,5 h.

**NCH - Non-class hours:** 1,5 h.

**TH - Total hours:** 4 h.

**RGB394** [!] *Realiza una presentación oral del proyecto, justificando las soluciones propuestas con argumentos elaborados y precisos, y haciendo un uso correcto, inclusivo y no discriminatorio del lenguaje.*

**LEARNING ACTIVITIES**

	<i>CH</i>	<i>NCH</i>	<i>TH</i>
Carrying out/resolving projects/challenges/cases, etc. to provide solutions to problems in interdisciplinary contexts, real and/or simulated, individually and/or in teams	2,5 h.	1,5 h.	4 h.

**EVALUATION SYSTEM**

Presentation and defence of exercises, case studies, computer practical work, simulation practical work, laboratory practical work, term projects, end of degree project, master's thesis, challenges and problems

*W*

100%

**MAKE-UP MECHANISMS**

Observation (technical capacity, attitude and participation)

**CH - Class hours:** 2,5 h.

**NCH - Non-class hours:** 1,5 h.

**TH - Total hours:** 4 h.

**RGB321** [!] *Conoce y comprende las peculiaridades en cuanto a normativas y certificaciones de los productos sanitarios*

LEARNING ACTIVITIES	CH	NCH	TH
Development and writing of records, reports, presentations, audiovisual material, etc. on projects/work experience/challenges/case studies/experimental investigations carried out individually and/or in teams		8,25 h.	8,25 h.
Conducting tests, giving presentations, presenting defences, taking examinations and/or doing checkpoints	12 h.	7 h.	19 h.
Presentation by the teacher in the classroom, in participatory classes, of concepts and procedures associated with the subjects	20 h.		20 h.

EVALUATION SYSTEM	W	MAKE-UP MECHANISMS
Reports on the completion of exercises, case studies, computer exercises, simulation exercises, laboratory exercises, term projects, challenges and problems	20%	Individual written and/or oral tests or individual coding/programming tests
Individual written and/or oral tests or individual coding/programming tests	80%	

**CH - Class hours:** 32 h.  
**NCH - Non-class hours:** 15,25 h.  
**TH - Total hours:** 47,25 h.

**RGB322** [!] *Aplica los conocimientos sobre certificaciones y normativas a la hora de diseñar productos sanitarios para su posterior comercialización*

LEARNING ACTIVITIES	CH	NCH	TH
Development and writing of records, reports, presentations, audiovisual material, etc. on projects/work experience/challenges/case studies/experimental investigations carried out individually and/or in teams		8,25 h.	8,25 h.
Conducting tests, giving presentations, presenting defences, taking examinations and/or doing checkpoints	12 h.	7 h.	19 h.
Presentation by the teacher in the classroom, in participatory classes, of concepts and procedures associated with the subjects	20 h.		20 h.

EVALUATION SYSTEM	W	MAKE-UP MECHANISMS
Reports on the completion of exercises, case studies, computer exercises, simulation exercises, laboratory exercises, term projects, challenges and problems	20%	Individual written and/or oral tests or individual coding/programming tests
Presentation and defence of exercises, case studies, computer practical work, simulation practical work, laboratory practical work, term projects, end of degree project, master's thesis, challenges and problems	20%	
Individual written and/or oral tests or individual coding/programming tests	60%	

**CH - Class hours:** 32 h.  
**NCH - Non-class hours:** 15,25 h.  
**TH - Total hours:** 47,25 h.

## CONTENTS

- 1.Context.
- 2.European legislative framework
- 3.AEMPS

---

4.Introduction

5.What is a medical device?

6.Various definitions

7.Economic agents: manufacturers, importers, distributors, authorised representatives and notified bodies

8.The UDI

9.Process of marketing a product in EU

1.Operating license

2.Product classification.

3.Technical documentation

4.Risk management

5.Clinical evaluation

6.Quality management system

7.Conformity assessment procedures

8.EC (EU) declaration of conformity and CE marking

9.EUDAMED Database

10.Infringements and sanctions.

## LEARNING RESOURCES AND BIBLIOGRAPHY

### Learning resources

Subject notes  
Moodle Platform

### Bibliography

Reglamento 745/2017 del Parlamento Europeo y del Consejo, de 5 de abril de 2017 sobre los productos sanitarios.  
UNE-EN-ISO 13485:2016 Sistemas de gestión de calidad.  
Requisitos para fines reglamentarios  
UNE-EN-ISO 14971:2019 Gestión de riesgo de productos sanitarios  
PS1/2019 Instrucciones para la licencia de funcionamiento.