

MEDICAL UNIVERSITY – PLOVDIV
FACULTY OF PHARMACY

SYLLABUS
IN
MEDICAL DEVICES

Approved by the Department Council - Protocol №8/16.10.2024

Confirmed by the Faculty Council - Protocol № 09/13.11.2024

MEDICAL DEVICES

Syllabus

Discipline	Final exam/ semester	According to the Faculty of Pharmacy curriculum of MU-Plovdiv Academic hours				ECTS	Academic hours in semester	
		VIII semester					L	P
		Auditorium	Lectures	Practices	Non-auditorium			
Medical devices	VIII	60	30	30	60	4,0	30	30

DISCIPLINE:

Medical devices

TYPE OF DISCIPLINE ACCORDING TO THE UNIFORM STATE REQUIREMENTS:

Compulsory

LEVEL OF QUALIFICATION:

Master (M)

FORMS OF TRAINING:

Lectures, practical classes

YEAR OF TRAINING:

IV course

DURATION OF TRAINING:

One semester

ACADEMIC HOURS:

30 teaching hours of lectures, 30 teaching hours of practical classes

TECHNICAL EQUIPMENT APPLIED IN THE TRAINING:

Lectures, multimedia presentations, discussions, developing a thesis, practical exercises, solving practical cases, working with databases.

FORMS OF EVALUATION:

1. Current assessment during the semesters:

- colloquium;

- development of theses.
2. Semester exam (written and oral)

EVALUATION CRITERIA:

The grade is formed based on the examination – written and oral, and the colloquium results.

ASPECTS OF EVALUATION CRITERIA:

Participation in discussions, colloquium, development of theses.

SEMESTER EXAM:

Yes (written and oral examination)

STATE EXAM:

No

LECTURER:

Assoc. Prof. Stanislav Georgiev, PhD

Assoc. Prof. Daniela Grekova-Kafalova, PhD

Chief Assist. Prof. Radiana Staynova, PhD

DEPARTMENT:

Organisation and Economics of Pharmacy

ANNOTATION

The medical devices sector plays a crucial role in the diagnosis, prevention, monitoring, and treatment of diseases, as well as in improving the quality of life of people with disabilities. Regulatory requirements for medical devices, which establish market access rules, aim to ensure consumer safety on one hand and to stimulate innovation in the sector on the other. The innovativeness and wide variety of these products significantly contribute to enhancing the quality and effectiveness of healthcare.

An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typically, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.

The discipline "Medical Devices" is mandatory for fourth-year students in the Pharmacy program. The objective of this discipline is to clarify the legal regulations concerning medical devices, including research and classification, market entry, safety, as well as their nomenclature, types, and intended uses; their characteristics; conditions and methods of use; changes that may occur during use and storage; procedures for their acceptance, packaging, and

transportation; and the methods for storing medical devices in the wholesale trade facilities and community and hospital pharmacies, in order to preserve their original qualities and properties. Practicals include demonstrations of the operation of the most commonly used medical devices available in pharmacies and healthcare facilities, discussions regarding the interpretation of results from self-diagnostic tests, clarification on the rules for working with medical devices, as well as handling public databases and registries.

BASIC AIMS OF THE DISCIPLINE

The main objectives of the discipline "Medical Devices" are to familiarize students with:

- The European legislative framework in the field of medical devices;
- The terminology, definitions, and key requirements related to the marketing authorization of medical devices;
- The manufacturing and clinical trials of medical devices;
- The Medical Devices Act and related regulations in Bulgaria;
- The nomenclature of medical devices, their intended use, packaging, and storage;
- The use of medical devices available in pharmacies and healthcare facilities.

EXPECTED RESULTS

Upon completion of the training, students should possess the following knowledge and skills:

- Familiarity with the terminology, key definitions, and legislative requirements in the EU and Bulgaria related to medical devices;
- Knowledge of the primary classes of medical devices used in medical practice and their application for prevention, treatment, and diagnosis of diseases;
- Understanding of the various types of software and programs designed to support the operation of medical devices;

- A fundamental knowledge of the requirements for quality, safety, biocompatibility, biotolerance, reliability, and efficacy of medical devices, as well as their storage and dispensing;
- Ability to navigate public registers and databases and to evaluate the characteristics and functionality of medical devices in various fields;
- Capability to provide information and training to patients regarding the proper use of certain groups of medical devices available in pharmacies.

LECTURES

Course IV, Semester VIII

№	T E M A	Брой часове
1	Introduction. Historical development and contemporary trends in the global and European medical device market. Medical devices as part of the healthcare and pharmaceutical system. The role of the pharmacist in the distribution of medical devices.	2
2	European regulatory framework for medical devices. Regulation (EU) 2017/745 on medical devices.	2
3	European regulatory framework for medical devices. Regulation (EU) 2017/746 for “in vitro” diagnostic medical devices.	2
4	Regulatory framework for medical devices in Bulgaria. Medical Devices Act. General medical devices regulatory framework of the EU and Bulgaria.	2
5	Classification of medical devices. Key terms and definitions. Requirements for packaging and labeling.	2
6	International standards for medical devices. Definitions of standards. Conformity assessment. ISO standards.	2
7	Clinical trials of medical devices.	2
8	Regulation of the market access to medical devices. Market authorization.	2
9	Digital technology-based medical devices. Digital transformation in the field of medical devices.	2
10	Design of medical devices. Materials and technologies used in manufacturing.	2

11	Financial access to medical devices in Bulgaria. Medical devices reimbursed by the National Health Insurance Fund (NHIF) budget.	2
12	Financial access to medical devices in Bulgaria. Medical devices covered by healthcare establishments' budgets. Medical devices funded by the state budget outside mandatory health insurance.	2
13	Medical devices in pharmacy practice. “In vitro” diagnostic medical devices.	2
14	Health technology assessment of medical devices.	2
15	Medical equipment and software. Imaging diagnostics, laboratory equipment, and medical technology.	2

Total: 30 hours

PRACTICES

Course IV, Semester VIII

№	Т Е М А	Брой часове
1	Medical devices – regulatory framework, definition, and classification. CE marking. Practical cases for determining the type of medical devices.	2
2	Medical Devices in Endocrinology. Glucometers, Continuous glucose monitoring systems, Insulin pens, Insulin pumps	2
3	Medical Devices in Pulmonology. Types of inhaler devices and guidelines for their use, Peak flow meters (spirometers). Nebulizers	2
4	Medical Devices in Pediatrics. Nasal aspirators. Thermometers. Medical devices used for skin irritations, etc.	2
5	Medical Devices in Cardiology. Lipid meters. Work with automatic, semi-automatic, and manual blood pressure measuring devices	2
6	Medical Devices in Orthopedics. Orthosis, orthopedic insoles, etc.	2
7	Medical Devices in Otorhinolaryngology. Devices with mechanical action on the functions of the upper respiratory tract	2
8	Medical Devices in General Medicine. Devices for injection, infusion, and suction; needles, sutures, etc.	2
9	Medical Devices for Wound Treatment. Dressing materials, products for treating and healing wounds	2

10	Medical Devices in Ophthalmology. Contact lenses – types, materials, applications. Products for cleaning and storing contact lenses. Medical devices for eye lubrication	2
11	Medical Devices in Gastroenterology and Urology. Catheters. Types of stomas	2
12	Medical Devices in Obstetrics and Gynecology. Intrauterine devices (IUDs), pregnancy tests, ovulation tests, etc.	2
13	Digital Technology-Based Medical Devices	2
14	Colloquium on Topics 1-13	2
15	European and National Databases and Registries for Medical Devices. Practical tasks.	2

Total: 30 hours

LECTURES – THESIS

LECTURE № 1 – 2 hours

INTRODUCTION

1. Historical development and contemporary trends in the global and European medical device market.
2. Medical devices as part of the healthcare and pharmaceutical system.
3. The role of the pharmacist in the distribution of medical devices.

LECTURE № 2 – 2 hours

EUROPEAN REGULATORY FRAMEWORK FOR MEDICAL DEVICES. REGULATION 2017/745

1. General regulatory framework of the EU and Bulgaria.
2. Regulation 2017/745 on medical devices.
3. Structure of the regulation.
4. Scope, content, and key concepts.
5. European Database for Medical Devices (EUDAMED).

LECTURE № 3 – 2 hours

EUROPEAN REGULATORY FRAMEWORK FOR MEDICAL DEVICES. REGULATION 2017/746 FOR “IN VITRO” DIAGNOSTIC MEDICAL DEVICES.

1. Regulation 2017/746 for “in vitro” diagnostic medical devices.
2. Regulation 2017/745 on medical devices.
3. Structure of the regulation.
4. Scope, content, and key concepts.

LECTURE № 4 – 2 hours

REGULATORY FRAMEWORK FOR MEDICAL DEVICES IN BULGARIA

1. Medical Devices Act – objectives, scope, structure.
2. Conditions and procedures for placing medical devices on the market.
3. Manufacturing, wholesale, and retail trade of medical devices in Bulgaria.

4. Conditions and procedures for issuing conformity assessment permits for medical devices.
5. Subordinate regulatory acts related to the Medical Devices Act.

LECTURE № 5 – 2 hours

CLASSIFICATION OF MEDICAL DEVICES. REQUIREMENTS FOR PACKAGING AND LABELING

1. Medical devices- definition.
2. Classification of medical devices – examples.
3. Risk classification (CLASS I, CLASS IIB, CLASS III, CLASS ABCD).
4. Data and trends characterizing the global, European, and Bulgarian medical device markets.
5. Requirements for packaging and labeling.

LECTURE № 6 – 2 hours

INTERNATIONAL STANDARDS FOR MEDICAL DEVICES

1. International Standards for Medical Devices
 - ISO 13485 (Quality management systems for medical devices)
 - ISO 14971 (Risk management)
 - ISO 15223-2 (Symbols for labeling medical devices, information for users)
 - ISO 10993 (Biocompatibility of medical devices)
 - ISO 62304 (Software lifecycle processes for medical devices)
2. Declaration of conformity. Patents for medical devices.

LECTURE № 7 – 2 hours

CLINICAL TRIALS OF MEDICAL DEVICES

1. Conditions and procedures for conducting clinical trials of medical devices.
2. Post-market surveillance system.
3. Ensuring the safety and efficacy of medical devices.
4. Materiovigilance and reactovigilance.

LECTURE № 8 – 2 hours

REGULATION OF THE MARKET ACCESS TO MEDICAL DEVICES. MARKET AUTHORIZATION

1. Regulatory requirements for marketing authorization of medical devices
2. Registration and marketing authorization procedures.
3. Notified bodies.
4. Technical documentation for medical devices.
5. Nomenclature requirements for marketing authorization

LECTURE № 9 – 2 hours

DIGITAL TECHNOLOGY- BASED MEDICAL DEVICES. DIGITAL TRANSFORMATION IN THE FIELD OF MEDICAL DEVICES.

1. Types of medical devices based on digital technologies and their applications
2. Regulatory access to medical devices based on digital technologies
3. Financial access to medical devices based on digital technologies

LECTURE № 10 – 2 hours

DESIGN OF MEDICAL DEVICES

1. Materials and technologies used in manufacturing
2. Design, research, implementation, and testing of products
3. Lifecycle of a medical device

LECTURE № 11 – 2 hours

FINANCIAL ACCESS TO MEDICAL DEVICES IN BULGARIA

Medical devices reimbursed by the NHIF budget.

1. Regulatory framework
2. Procedure for prescribing medical devices reimbursed by NHIF for outpatient medical care
3. Specific requirements for medical devices reimbursed by NHIF for individual medical practice
4. Dispensing prescriptions for medical devices within the EU

LECTURE № 12 – 2 hours

FINANCIAL ACCESS TO MEDICAL DEVICES IN BULGARIA

Medical devices covered by healthcare establishments' budgets. Medical devices funded by the state budget outside mandatory health insurance.

1. Regulatory Framework
2. Medical Devices funded by the budgets of healthcare institutions
3. Types of medical devices in hospital practice
4. Medical devices funded by the state budget outside mandatory health insurance.

LECTURE № 13 – 2 hours

MEDICAL DEVICES IN PHARMACY PRACTICE

“In-vitro” diagnostic medical devices.

1. MDs Used in Gynecology
2. MDs Used in Urology
3. MDs Used in Otorhinolaryngology
4. MDs Used in General Medicine
5. MDs Used in Cardiology
6. MDs Used in Orthopedics
7. MDs Used in Pulmonology
8. MDs Used in Endocrinology

LECTURE № 14 – 2 hours

HEALTH TECHNOLOGY ASSESSMENT OF MEDICAL DEVICES

1. Regulatory Framework
2. Pricing of medical devices
3. Reimbursement of medical devices

LECTURE № 15 – 2 hours

MEDICAL EQUIPMENT AND SOFTWARE

Imaging diagnostics, laboratory equipment, and medical technology.

1. Medical Equipment
2. Categories of medical equipment
3. Medical devices for Diagnostic imaging

4. Medical Devices for Laboratory equipment
5. Medical Software

PRACTICES –THESIS

PRACTICAL CLASS № 1 – 2 hours

MEDICAL DEVICES – REGULATORY FRAMEWORK, DEFINITION, AND CLASSIFICATION

CE marking. Practical cases for determining the type of medical devices.

1. Review and Analysis of Regulatory Documents in the Field of Medical Devices
2. Definition and Classification
3. CE marking
4. Practical Cases for Determining the Type of Medical Devices.

PRACTICAL CLASS № 2 – 2 hours

MEDICAL DEVICES IN ENDOCRINOLOGY

1. Practical Work with an “in-vitro” diagnostic medical device for measuring blood glucose – Glucometer
 - Device
 - Importance of blood glucose concentration for human health
 - Guidelines for accurate measurement of blood glucose concentration
2. Continuous Glucose Monitoring Systems
 - Essence, Device, Types
 - Applications and Benefits
3. Insulin Pens – Types, Device, Application.

PRACTICAL CLASS № 3 – 2 hours

MEDICAL DEVICES IN PULMONOLOGY

1. Introduction to the Main Methods of Inhalation of Substances and Medications by Humans.
2. Guidelines for Inhalation of Substances and Medications by Humans.
3. Types of Inhalers – Device and Usage.
4. Working with Metered-Dose Inhalers, Compressor Inhalers, and Ultrasonic Inhalers.
5. Comparison of the Characteristics of Different Types of Inhalers. Storage and Maintenance.

PRACTICAL CLASS № 4 – 2 hours

MEDICAL DEVICES IN PEDIATRICS

1. Nasal Aspirators – Types, Advantages and Disadvantages, Operating Guidelines.
2. Electro-Mechanical Medical Devices. Types of Thermometers and Usage Specifications
 - Contact and Non-Contact Electronic Thermometers – Advantages and Disadvantages
 - Methods and Guidelines for Accurate Measurement of Body Temperature
 - Comparison of the Characteristics of Different Types of Thermometers
3. Medical Devices Used for Skin Irritations.

PRACTICAL CLASS № 5 – 2 hours

MEDICAL DEVICES IN CARDIOLOGY

1. Working with a Device for Measuring Blood Cholesterol – Lipid Meter
 - Device
 - Importance of Cholesterol Concentration in Blood for Human Health
 - Guidelines for Accurate Measurement of Cholesterol Concentration in Blood
2. Theoretical Introduction to the Main Methods of Measuring Blood Pressure (Auscultatory and Oscillometric).
3. Discussion and Establishment of Guidelines for Accurate Measurement of Blood Pressure.
4. Individual Measurement of Blood Pressure with a Mechanical Device.
5. Individual Measurement of Blood Pressure with a Semi-Automatic Digital Device.
6. Individual Measurement of Blood Pressure with an Automatic Digital Device. Comparison of the Characteristics of Different Types of Devices. Storage and Maintenance.

PRACTICAL CLASS № 6 – 2 hours

MEDICAL DEVICES IN ORTHOPEDICS

1. Orthoses
2. Orthopedic Insoles
3. Assistive Devices
4. Medical Devices Used in Sports.

PRACTICAL CLASS № 7 – 2 hours

MEDICAL DEVICES IN OTORHINOLARYNGOLOGY

1. Medical Devices with Mechanical Action to Influence the Functions of the Upper Respiratory Tract
 - Medical Devices – Tablets. Examples
 - Medical Devices – Nasal and Throat Sprays. Examples
 - Medical Devices – Syrups. Examples
2. Medical devices for softening and removing Earwax (Cerumen) from the ear
3. Oscopes

PRACTICAL CLASS № 8 – 2 hours

MEDICAL DEVICES IN GENERAL MEDICINE

1. Medical Devices for Injection, Infusion, and Aspiration, Needles, Sutures, etc.
2. Types of Needles, Syringes, Pipettes, Sutures.
3. Practical Work on Characterizing Surgical Needles and Sutures, as well as Infusion Devices.

PRACTICAL CLASS № 9 – 2 hours

MEDICAL DEVICES IN WOUND TREATMENT

1. Wound – Definition and Key Concepts.
2. Demonstration of Various Devices for Wound Treatment.
3. Demonstration of Various Devices for Corns and Blisters.
4. Demonstration of Liquid Dressings.
5. Use and Role of silver in medical devices for wound treatment.

PRACTICAL CLASS № 10 – 2 hours

MEDICAL DEVICES IN OPHTHALMOLOGY

Contact lenses – types, materials, applications. Products for cleaning and storing contact lenses. Medical devices for eye lubrication

1. Contact Lenses – Types of Contact Lenses According to Their Purpose and Wearing Duration.
2. Inserting and Removing Contact Lenses, Safety Guidelines for Wearing Contact Lenses.
3. Application of Medical Devices for Cleaning and Storing Contact Lenses.
4. Types of Solutions for Lenses, Use of Lens Solutions for Cleaning and Storing Devices, Safety Guidelines for Their Use.
5. Medical devices for eye lubrication

PRACTICAL CLASS № 11 – 2 hours

MEDICAL DEVICES IN GASTROENTEROLOGY AND UROLOGY

1. Urethral Catheters.
2. Tests for Urinary Infections and Test Strips for Urine Analysis.
3. Examination of Medical Devices for Stoma Patients – Urostomy Bags, Colostomy Bags, Gastrostomy Devices.

PRACTICAL CLASS № 12 – 2 hours

MEDICAL DEVICES IN OBSTETRICS AND GYNECOLOGY

1. Pregnancy Tests:
 - Pregnancy Test Strips, Cassette Pregnancy Tests, Pen-Type Pregnancy Tests;
 - Characteristics and Usage Instructions;
 - Comparison of the Characteristics of Different Types of Tests, Accuracy of Pregnancy Tests.
2. Ovulation Tests.
 - Discussion and Establishment of Requirements and Guidelines for Accurate Ovulation Detection.
3. Introduction to Various Types of Intrauterine Devices (IUDs) and Other Implantable Medical Devices for Contraception.
4. Therapeutic Pessaries and Vaginal Ovules.

PRACTICAL CLASS № 13 – 2 hours

DIGITAL TECHNOLOGY- BASED MEDICAL DEVICES

1. Wearable Health Monitors
2. Telemedicine Platforms
3. Remote Patient Monitoring Devices
4. "Smart" Inhalers
5. Implantable Medical Devices with Digital Applications
6. Artificial Intelligence Algorithms

PRACTICAL CLASS № 14 – 2 hours

COLLOQUIUM

1. Colloquium on Topics 1 – 13.

PRACTICAL CLASS № 15 – 2 hours

EUROPEAN AND NATIONAL DATABASES AND REGISTRIES FOR MEDICAL DEVICES

1. Working with the Electronic Database for Medical Devices of the Bulgarian Drug Agency
2. Working with the European Medical Device Database (EUDAMED)

BIBLIOGRAPHY

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2. Пъпанов Ст, Петкова Е, Михайлова А. Учебник по Медицински изделия, Изд. FastPrintBooks, 2020, ISBN 978-619-236-206-5
3. Григоров, Е., Медицински изделия – правно регулиране в България. МУ-Варна, Принтзоун ООД, 2015.
4. Григоров, Е., Е. Костов, Х. Лебанова, И. Гетов, Пазарно проучване на медицински изделия прилагани за аерозолотерапия, Обща медицина, 2013 (15) 2, 36-39.
5. Григоров, Е., Х. Лебанова, Е. Насева, И. Гетов, Проучване на нагласите за измерване на кръвно налягане сред посетителите в аптеки в София, Сърдечно-съдови заболявания, 2012 (43) 2, 43-47.
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9. Герасимов, Н., Ст. Сопотенски, Г. Петрова. Развитие на Европейското законодателство в областта на медицинските изделия – основа за безопасни, ефективни и иновативни медицински изделия в полза на пациентите и медицинските специалисти, Медицински мениджмънт и здравна политика, 2014 (45) 4, 26-41.
10. Министерство на Здравеопазването. Закон за медицинските изделия, (Обн. ДВ. бр.46 от 12 Юни 2007г.)
11. Министерство на Здравеопазването. Наредба за съществените изисквания и процедурите за оценяване на съответствието със съществените изисквания на ин витро диагностичните медицински изделия (Приета с ПМС № 184, обн. ДВ. бр.65 от 10 август 2007 г.)
12. Министерство на Здравеопазването. Наредба за условията и реда за блокиране, изтегляне и/или унищожаване на медицински изделия.(Обн. ДВ бр. 97 от 11 ноември 2008 г.)
13. Закон за лекарствените продукти в хуманната медицина (ЗЛПХМ) в сила от 13.04.2007 г. (чл. 219, чл. 225, чл. 238, § 22 от преходните и заключителните разпоредби);

14. Национален рамков договор № РД-НС-01-4 от 23 декември 2019 г. за медицинските дейности между Националната здравноосигурителна каса и Българския лекарски съюз за 2020 – 2022 г. (чл. 2, чл. 30, Глава 11);
15. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.
16. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices.
17. European commission, Guidelines on medical devices, Brussels, Belgium, 2005.
18. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
19. Council Directive 90/385/EEC OF 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices
20. CRDH, Medical device Use-safety: Incorporating human factors engineering into risk management, CDRH, USA, 2000
21. WHO, Medical device regulation.(Global overview and guiding principles), Geneva, 2010.

CONSPECTUS

1. European regulatory framework for medical devices. Regulation (EU) 2017/745 on medical devices.
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3. International standards for medical devices.
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18. Medical devices in Ophthalmology.

19. Medical devices in Urology, Gynecology, and Gastroenterology.
20. Medical equipment and software. Imaging diagnostics, laboratory equipment, medical technology.

PREPARED BY: Assoc. Prof. D. Kafalova, PhD.....

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