

**Катедра по организация и
икономика на фармацията**

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**Department of Organisation
and Economics of Pharmacy**

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**CONSPECTUS
OF
MEDICAL DEVICES**

1. European regulatory framework for medical devices. Regulation (EU) 2017/745 on medical devices.
2. European regulatory framework for medical devices. Regulation (EU) 2017/746 on “in vitro” diagnostic medical devices.
3. International standards for medical devices.
4. Medical Devices Act in Bulgaria – purpose, scope, structure.
5. Clinical trials of medical devices. Methods for assessment of the efficacy and safety of medical devices.
6. Medical devices – definition, classification, packaging and labeling.
7. Health technology assessment for medical devices. Financial access to medical devices in Bulgaria – pricing and reimbursement.
8. Design of medical devices. Materials and technologies used in manufacturing.
9. Regulatory access of medical devices to the market. Marketing authorization.
10. Digital technology-based medical devices. Digital transformation in the field of medical devices.
11. Medical devices reimbursed by the National Health Insurance Fund (NHIF) budget.
12. Medical devices reimbursed by the budget of health establishments.
13. Medical devices funded by the state budget outside mandatory health insurance.
14. Medical devices in Cardiology and Endocrinology.
15. Medical devices in Pulmonology. Types of inhalation devices. Electro-mechanical medical devices – Nebulizers. Devices with mechanical action on the functions of the upper respiratory tract
16. Medical devices for Wounds treatment.

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17. Medical devices in General Medicine and Orthopedics.
18. Medical devices in Ophthalmology.
19. Medical devices in Urology, Gynecology, and Gastroenterology.
20. Medical equipment and software. Imaging diagnostics, laboratory equipment, medical technology.

The syllabus was approved by the Department council with Protocol №04/22.05.2024

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/Head of Department of Organisation and Economics of Pharmacy/**