Co-funded by the Erasmus+ Programme of the European Union	**BeWell – Medical Device Regulation Matrix**		
EQF Level	**5**	**ESCO**	**Medical device regulations (knowledge)[1]**
Aggregated Units of Learning Outcomes	**BeWell – NEOP 4**		**Medical Device Regulation**

Co-funded by the Erasmus+ Programme of the European Union		
Generic Title of the Training programme:	**NEOP 4 – Medical Device Regulation**	
Description:	**This Training programme provides learners with essential knowledge of EU Regulation 2017/745 on medical devices. It covers the importance, scope, and compliance requirements of the regulation, ensuring that learners understand the fundamental legal and safety considerations in medical device usage and clinical investigation.**	
EQF Level:	**5**	

[1] **Description:** The set of national and international regulations with regards to the manufacture, safety, and distribution of medical devices.

<table>
<tr><th colspan="4">Learning Outcomes</th></tr>
<tr><td rowspan="2">NEOP 4 – Medical Device Regulation</td><td rowspan="2">Training Module # in MOOC</td><td colspan="2">Competence (Autonomy and responsibility)</td></tr>
<tr><td>Knowledge</td><td>Skills</td></tr>
<tr><td rowspan="4">4.1 Ensuring Compliance with Medical Device Regulations</td><td rowspan="4">Module 1 and Module 2</td><td colspan="2">Is able to apply the fundamental principles of EU Regulation 2017/745 to ensure compliance in medical device usage and clinical investigation.</td></tr>
<tr><td>Knows the importance, scope, and key provisions of EU Regulation 2017/745 concerning medical devices.</td><td>Identifies the classification of medical devices under the regulation.</td></tr>
<tr><td rowspan="2">Can identify key components of the regulation, including its application to medical devices.</td><td>Explains the compliance requirements for medical device approval and market access in the EU.</td></tr>
<tr><td>Recognises the role of clinical investigation in ensuring medical device safety and effectiveness.</td></tr>
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