

“The requirements of the new Regulation 2017/745 for medical devices”

The Upper Silesian Accelerator for Commercial Enterprises Ltd. together with the Chain REACTIONS project partners would like to invite you to another workshop organised within the framework of the virtual competence centre, which is part of the pilot action and activities of the project: CHAIN REACTIONS "Driving smart industrial growth through value chain innovation".

The workshops will not only provide knowledge about the MDR regulation, but will also give you an insight into the possibilities of cooperation in the field of medical devices in Veneto and Upper-Silesia.

Participation is free of charge and places are limited.

Agenda:

10:00 – 10:30	CHAIN REACTIONS “Driving smart industrial growth through value chain innovation” Cooperation opportunities in the area of medical devices in the regions – pilot action. Overview of the Veneto and Upper-Silesia ecosystems
10:30 – 14:30	Workshop: The requirements of the new Regulation 2017/745 for medical devices Expert: Małgorzata Gonsior-Kustosz (DevGoMed)

Detailed themes:

- Definitions,
- common technical specifications,
- general obligations of the manufacturer,
- general obligations of importers
- responsibility for compliance with regulatory requirements,
- classification of medical devices,
- conformity assessment procedures,
- conformity assessment control mechanism,
- voluntary change of notified body,
- clinical examinations – Authorizations,
- products presenting a health and safety risk at national level,
- overview of attachments.