

Workshop Title:

“Vademecum MDR” – “The Handbook for MDR – Guidelines and Templates for Market Access of Orthopaedic Devices According to the Medical Device Regulation

Workshop Organizer:

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Brief Description:

With the new MDR (Medical Device Regulation) companies in the sector of rehabilitation technology are facing various challenges. Especially for small companies and, distributors and importers help is needed to meet these complex requirements. In cooperation with the Austrian Economic Chamber and industry representatives, MDR experts of the University of Applied Sciences Technikum Vienna created a handbook with simple structured templates for companies in the field of rehabilitation engineering.

Abstract:

With the new MDR (Medical Device Regulation) companies in the sector of rehabilitation technology are facing various challenges. Especially for small companies, distributors and importers help is needed to meet these complex requirements. In cooperation with the Austrian Economic Chamber and industry representatives, MDR experts of the University of Applied Sciences Technikum Vienna created a handbook with simple structured templates for companies in the field of rehabilitation engineering e.g. orthopaedic shoemakers and prosthetists. In the course of the workshop the handbook and templates which are devised to be applicable in daily business are presented. Use cases such as different medical products made by small and medium-sized enterprises, help better understand the material. A special focus lies on “custom-made devices”. After the introduction participants are encouraged to ask questions and write down their personal or company-specific challenges with the MDR. The challenges are then clustered to see similarities and ranked based on their frequency of occurrence. Five to seven “main challenges” will be used to form working groups. Discussions will help, understand how to use the guidelines to handle the group-specific topics. The working groups are encouraged to use their own company-specific products as use cases in the provided templates. After this interactive part, a member of each group will be asked to present the outcome. Lastly, the moderators will give a comprehensive summary and repeat the most important findings of the session. After completing the workshop, participants are able handle problems associated with the MDR in their own companies. With the usage of simple structured templates small companies and start-ups should be able to overcome barriers concerning market access of medical products. A positive side effect of this kind of workshop is international networking.