PHYSIO-LOGIC
Accelerated Medical Device Approval

המכללה ליצוא ולשיווק בינלאומי

מכון היצוא

Successful Transition to the New EU CE Marking Regulation (MDR)

Guest speakers from: Team-NB, TUV-SUD & GMED/LNE

HYBRID SEMINAR | Tuesday 21.12.21 | 09:00 – 16:30

Agenda

Introduction to the new EU MDR. When, where and why?
Mr. Gadi Ginot, CEO Physio-Logic

- Developing Technical Documentation to the MDR requirements
  Dr. Tamar Katzav, VP Medical Device Practice, Physio-Logic
- Successful transition of Quality Management System (QMS) to the MDR
  Ms. Yael Goldbrener, VP Q&R Services, Physio-Logic
- Eudamed – State of play (On Zoom)
  Ms. Françoise Schlemmer, Director, Team-NB
- Clinical Investigations under the MDR
  Ms. Inessa Dolnik, Head of Clinical Services, Physio-Logic
- Manufacturer perspective on transition to the MDR
  Ms. Maya Naftali, VP of Endosurgery, QMD
- MDR expectations from Dental and Orthopedic devices (On Zoom)
  Dr. Katalin Meszaros, Senior Clinical Expert for Dental Devices, TÜV SÜD UK
- EU MDR expectations from high-risk devices (focus on Orthopedic devices)
  Mr. Matthias Fink, M.D., TÜV SÜD America (On Zoom)
- Notified Body expectations from software and AI based medical devices manufacturers under the MDR (On Zoom)
  Dr. Sara Jafari, GMED North America

Limited places, First come First served
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