Title: Compliance to EU MDR General Safety and Performance Requirements (GSPRs) by Application of Standards
Date Tuesday, 01 September 2020 (9:00 AM) – Tuesday, 01 September 2020 (3:15 PM) Eastern Time (US & Canada)

Facilitators:

- **Bassil Akra, CEO QUNIQUE GmbH**
- **Sabina L. Hoekstra-Van den Bosch, PharmD FRAPS TÜV SÜD Product Service Gmbh**
- **Martin Witte Global Director, TÜV SÜD Product Service GmbH**
- **Peter Bowness, Technical Team Manager, British Standards Institution**
- **Dominik Herzog, Managing Director, TentaMedix GmbH**
- **Christoph Lindner, Teamleader Medical Device Testing, TUV Sud Product Service GmbH**
- **Christian Johner**
- **Dr. Andreas Purde, Director, TÜV SÜD Product Service GmbH**

Agenda:

Day 1

9:00 – 9:10 AM EST	**Workshop Start – Welcome and Opening (10 min)** **• Dr. Bassil Akra** **• Sabina Hoekstra**
9:10 – 9:35 AM EST	**GSPR of the Medical Device Regulation** **• Martin Witte (25 min)**
9:35 AM – 10:15 AM EST	**Risk Management Requirements ISO 14971 (25 mins)** **• Peter Bowness**
10:15 – 10:30 AM EST	**Q&A** **• All speakers**
10:30 – 10:15 AM EST	**15 minute break**
10:45- 12:15 PM EST	**Comply with single fault safety and cybersecurity Requirements of the MDR - A practical approach (90 min)** **• Prof. Dr. Christian Johner** **• Dr. Andreas Purde**
12:15 -12:45 PM EST	**Lunch Break (30 min)**
12:45- 2:15 PM EST	**Biocompatibility Requirements ISO 10993 - View of a notified body and a test lab (90 min)** **• Dr. Dominik Herzog** **• Dr. Christoph Lindner**
2:15-3:15 PM EST	**Q&A and Conclusions** **• All speakers**
3:15 PM EST	**Workshop Ends**