Title: EU MDR Annex II Technical Documentation Details: Too Much? Too Little? What is "Just Right"?
Date Monday, 21 September 2020 (9:00 AM) – Tuesday, 22 October 2020 (2:00 PM) Eastern Time (US & Canada)

Facilitators:

- Virginia Swassing Executive Director, Device and Diagnostic Regulatory
- Janet Whipple Partner, Medical Device & In vitro Diagnostics, Validant
- Julien Senac, Ph.D. Director, IVD Global Focus Team, TÜV SÜD
- Deborah Madsen Consultant, Madsen QRC
- Sharmila Gardner Regulatory Lead, BSI

Agenda:

Day 1

8:45 AM EST	**Attendees are expected to be logged into the webinar and placed in a virtual waiting room**
9:00 AM EST	**Start of the webinar**
9:00- 9:30 AM EST	**Speaker presentations**
9:30- 10:30 AM EST	**Case Study Introduction and Structured Q&A (Annex II Sections 1-2)**
10:30- 10:45 PM EST	**15-minute break**
10:45- 11:15 AM EST	**Speaker presentations**
11:15 AM- 12:30 PM EST	**Case Study Discussion and Structured Q&A (Annex II Sections 3-4)**
12:30- 1:00 PM EST	**Summary of Day 1 and Preparation for Day 2**

Day 2

8:30 AM EST	**Speakers are expected to be logged into the webinar**
8:45 AM EST	**Attendees are expected to be logged into the webinar and placed in a virtual waiting room**
9:00 AM EST	**Start of the webinar**
9:00- 9:30 AM EST	**Speaker presentations**
9:30- 10:30 AM EST	**Case Study Discussion and Structured Q&A (Annex II Sections 5-6)**
10:30- 10:45 AM EST	**15-minute break**
10:45- 11:15 AM EST	**Speaker presentations**
11:15 AM- 12:30 PM EST	**Case Study Discussion and Structured Q&A (All Sections – follow-up questions)**
12:30- 1:00 PM EST	**Summary of Day 2 and Wrap up of workshop**