Organizer:

香港醫療及保健器材行業協會
Hong Kong Medical and Healthcare Device Industries Association

Co-organizer:

bsi.

Webinar on "In Vitro Diagnostic Regulation (IVDR)"

The expectation of a Notified Body in review of technical documentation under IVDR certification
The perspective of clinical evidences for performance evaluation from a Notified Body

The IVDR, which replaces IVD Directive (98/79/EC), marked the start of the transition period for manufacturers selling IVD devices into Europe.

A required part of conformity assessment and CE Marking is the need for Technical Documentation. IVD manufacturers who have no experience for an IVDD certification reviewed by Notified Body struggle with how to prepare technical documentation under IVDR.

On the other hand, performance evaluation and clinical evidence is the most challenging part. The terms are different but quite similar to MDR which make confusion to a manufacturer, especially the person who has MDD / MDR experience before.

In this webinar, Medical Device Expert from BSI, Ms. Hailey Chu will introduce the structure of technical documentation and the aspects of performance evaluation in IVDR.

Date	19 June 2020 (Friday)
Time	14:30 – 16:00
Format	Online (access link will be sent in an separate email for successful registration)
Speaker	Ms. Hailey Chu, Technical Specialist & Scheme Manager, BSI global IVD team
Language	Mandarin
Fee	**Member: HK$150** **Non-member: HK$200**
Enrolment	Please *Click Here* for registration on or before **12 June 2020**
Payment:	1. Send the crossed cheque to "**Hong Kong Medical and Healthcare Device Industries Association Limited**" to Room 4, Unit 601, Core Building 1, Hong Kong Science Park, Pak Shek Kok, New Territories, Hong Kong. (Attn: Cathy Wong) OR 2. Bank-in the fee to the Association Account at: **534-440243-001(HSBC) and email the bank-in slip to: info@medicaldevice.org.hk on or before 12 June 2020**.
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