

## Seminar on “Update on European Medical Device Regulation (MDR) (2017/745)”

The new European Medical Device Regulation (MDR) 2017/745 has been published to replace the existing Medical Device Directive (93/42/EEC) and Active Implantable Medical Devices Directive (90/385/EEC). The MDR entered into force on 25 May 2017, marking the start of the transition period for manufacturers selling medical device into Europe. Are you ready for the changes ahead?

In this seminar, BSI Medical Device Expert Mr Lane Ji will introduce the key areas to note for the MDR transition challenges. Lane will also address the changes on the certification requirements of MDR.

Date	<b>7 August 2019 (Wed)</b>	
Venue	BSI Hong Kong 23 / F, Cambridge House, Taikoo Place, 979 King’s Road, Hong Kong	
Programme	2:15pm	<b>Registration</b>
	2:30-2:40pm	<b>Welcome Speech</b> Present by: Samson Tsoi, Vice Chairman, HKMHDIA
	2:40-2:50pm	<b>Opening Speech</b> Present by: Davis Leung, Senior Business Development Manager, BSI
	2:50-3:50pm	<b>EU MDR requirements on Clinical Evaluation, Post-market Surveillance (PMS), Post-market Clinical Follow-up (PMCF) and Periodic Safety Update Report (PSUR)</b> Present by: Lane Ji, Healthcare Director, BSI China Mr. Ji is the Specialist at medical device certification including ISO13485, ISO14971, MDD 93/42/EEC, IVDD 98/79/EC, Process validation, PMS & Vigilance, technical file, clinical evaluation.
		3:50-4:05pm
	4:05-4:50pm	<b>Changes on the Certification Requirements of MDR</b> Present by: Lane Ji, Healthcare Director, BSI China
	4:50-5pm	<b>Q&amp;A</b>
Fee	<b>Member: HK\$150</b>	Quota: 50 (First-come-first served)
	<b>Non-member: HK\$200</b>	Language: Mandarin / English
Application	Please <a href="#">Click Here</a> for registration on or before <b>31 July 2019</b> . Payment: 1. Send the crossed cheque to “ <a href="#">Hong Kong Medical and Healthcare Device Industries Association Limited</a> ” to LG1, HKPC Building, 78 Tat Chee Avenue, Kln, HK (Attn: Cathy Wong) 2. Bank-in the fee to the Association Account at: <b>534-440243-001(HSBC) and email the bank-in slip to: <a href="mailto:info@medicaldevice.org.hk">info@medicaldevice.org.hk</a> on or before 31 July 2019.</b>	
Enquiry	Cathy Wong Tel: (852)2191 0923 Email: <a href="mailto:info@medicaldevice.org.hk">info@medicaldevice.org.hk</a>	