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## Annual BSI Medical Devices Updates 2018

### Our Speakers



Hailey Chu

IVD Technical Specialist  
BSI Taiwan



Nathan Shipley

PPE Group Certification  
Manager, BSI UK

Performance in the global medical device sector remains challenging going into 2018, due to various regulatory and economic factors. The impending enforcement of the new Medical Devices Regulation (MDR) and In-Vitro Diagnostics Regulation (IVDR) have affected manufacturers' near-term expectations in the EU markets. The complexities of the new Regulations as well as new, stricter requirements for Notified Bodies have created near-term challenges for companies seeking and renewing CE Marking in Europe.

16 May  
9:00 am - 1:00 pm  
KL Hilton

Early Bird Promo Code  
"EBMED"  
MYR 150 / person before  
30th April

(RRP: MYR 300)

Tel +6 03 2242 4211  
info.malaysia@mail.com  
bsigroup.com.my

Outside of the EU, the transition of the Canadian Medical Device Conformity Assessment System (CMDCAS) to the Medical Device Single Audit Program (MDSAP) draws closer to its regulatory deadline in 2019 thus affecting all major markets participating in MDSAP. Post 2019, manufacturers seeking access to Canadian market must apply for MDSAP compliance as CMDCAS will be withdrawn.

To find out more, join us in our 2018 Annual Medical Devices market update and be prepared for the changes ahead.

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