Contact us
+44 345 080 9000
eu.medicaldevices@bsigroup.com

Regulatory review

Your monthly medical device update
March 2020

Coronavirus (COVID-19) update and impact on medical device assessments

The situation with regards to medical devices and the coronavirus (COVID-19) outbreak is evolving rapidly. With the safety and wellbeing of our clients and colleagues our highest priority, we want to advise you of our plans as an organization during this global health issue.

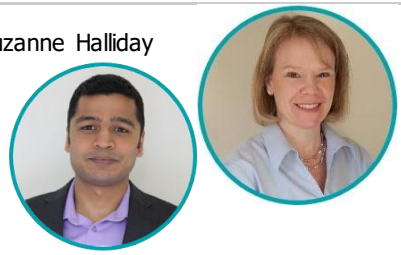
Taking into consideration the effects of the COVID-19 outbreak, we have reviewed our processes and put in place a contingency plan, the objective being to minimize the risk to BSI clients and colleagues whilst maintaining accreditation requirements and mitigating potential global trade risks.

Full details

Keep up-to-date on the industry latest with BSI Medical Devices webinars

Register to join our upcoming webinar:

EUDAMED and the Rolling Plan of the Commission with Dr Suzanne Halliday and Dr Jayanth Katta



29 April, 16.00 BST – Register now

30 April, 08.00 BST – Register now

30 April, 12.00 BST – Register now

All webinars

Listen back to our most recent webinar:

Symbols to be used on labelling (ISO 15223) and information to be provided by the manufacturer (ISO 20417) with Dr Peter Bowness

Listen back

Update on Taiwan's Technical Cooperation Programme (TCP II)

Following the official announcement on Friday 31 January 2020 that the UK has officially ceased to be a member of the European Union, we want to clarify what the impact is for Taiwan's Technical Cooperation Programme (TCP).

The UK has now entered a transition period in which it will negotiate future business and trade agreements with the EU. The transition period is due to end on Thursday 31 December 2020.

This means we will still be able to support our clients' applications to Taiwan under TCPII until the coming into force of TCPIII without any gaps. Both BSI UK (for UKAS certificates) and BSI NL (for RvA certificates) have applied to TFDA to be designated under TCPIII in the first run.

We'll inform you once we've received updates on our designation.

Read more

New MDR guidance

Read new guidance published by the Medical Device Coordination Group (MDCG) here:

- Guidance on significant changes regarding the transitional provision under Article 120 of the MDR
- Joint Implementation/preparedness plan on the new Medical Devices Regulation 2017/745 (MDR

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