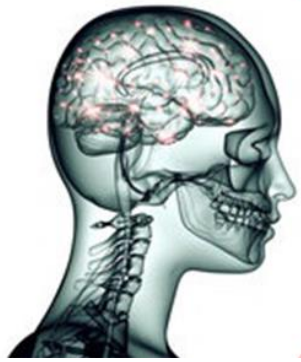
Email not displaying correctly?
View it in your browser

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



Regulatory review

Your monthly medical device update
March 2019

ISO 13485:2016 transition period ends

The ISO 13485:2016 transition deadline has now passed and certificates issued for the previous version of the standard are no longer valid.

If you didn't manage to complete a transition assessment before 28 February – unless prior to this deadline you booked an assessment to take place before 1 May 2019 – your current certificate will expire, and to maintain certification you'll need to re-apply and be quoted by a member of the commercial team. Contact us today.

If you have completed a transition assessment but still await your certificate, you'll maintain the natural pre-transition cycle/expiry and the same certificate number, provided the visit has been delivered and certificate issued before 31 August 2019. This also applies to manufacturers with an assessment booked before 1 May 2019.

Find out more

Do you know the requirements and your responsibilities for medical device vigilance reporting?

Our white paper provides a detailed comparison of the vigilance requirements of the MDSAP Regulatory Authorities and the EU MDR, so you can understand more about the requirements you need to meet.

Download now

Listen back to our webinars

Missed our latest webinars? They're now available on-demand so you can catch up at your convenience:

- Medical Devices Implant Cards – Kevin Madden
- Medicines and Biologics – Dr Jennifer Durrant

View on-demand

Concerned about Brexit?

It's posing many questions and uncertainties in our sector, so we have lots of information on our website to help keep you informed on the latest news and implications.

Visit Brexit page

---

bsi. | shop

...making excellence a habit.™