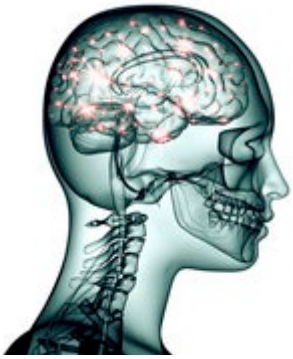
Contact us
+44 345 080 9000
bsigroup.com/medical



Regulatory review

Your monthly medical device update

December 2017

EN ISO 13485:2016 - The harmonized standard is here

ISO 13485:2016, the Medical Device Quality Management System standard, has been harmonized to the European Medical Devices Directives: MDD, AIMDD and IVDD. EN ISO 13485:2016 now replaces the previous version of the standard, EN ISO 13485:2012, in the EU Official Journal, with the date of 'cessation of presumption of conformity' of EN ISO 13485:2012 stated as 31 March 2019.

Standard harmonization allows manufacturers to use their compliance to the standard as evidence of

conformity to the requirements of relevant legislation. Manufacturers that hold CE certification with BSI to allow them to place devices on the market in Europe (but do not hold separate ISO 13485 certification) will be assessed to EN ISO 13485:2016 from **1 April 2019.** Manufacturers holding only ISO 13485 certification with BSI are required to transition to ISO 13485:2016/EN ISO 13485:2016 by **28th February, 2019.**

The harmonization of EN ISO 13485:2016 is another step towards compliance to the recently published Medical Devices and IVD Regulations, which will supersede the current Directives in three and five years, respectively. You can find out more about the standard's harmonization in our recent blog post.

BSI can now offer UKAS-accredited ISO 13485 certification to ISO 13485:2016 and to EN ISO 13485:2016. Talk to us to find out more.

BSI applies for MDR and IVDR Designation

BSI has submitted designation applications for the Medical Devices Regulation (Regulation (EU) 2017/745) and the In Vitro Diagnostic Regulation (Regulation (EU) 2017/746) to both the UK and The Netherlands Competent Authorities. 26 November 2017 was the first day that Notified Bodies were allowed to apply for designation under the MDR and IVDR, BSI were among the first wave of Notified Bodies to submit for both Regulations. The next step is for the respective Designating Authorities, MHRA in the UK and IGJ in The Netherlands, to review our application and write a preliminary report to be sent to the Commission so that they can schedule Joint Assessment audits of BSI.

BSI is proud to work towards designation for these critical Regulations and will continue to strive for excellence in our Notified Body activities over the transition period. We will ensure that you are kept up to date with the progression going forward.

Keep up to date with the latest developments by bookmarking our MDR and IVDR transition web pages:

bsigroup.com/mdr-revision

bsigroup.com/ivdr-revision

MDSAP, ISO 13485, MDR and IVDR: Are you ready for the changes?

This is a period of immense change for the Medical Device industry. Effective planning is essential for uninterrupted market access, and understanding the changes is the first step to ensure you accurately plan the time and resource required.

Use our timeline to review the upcoming changes and access resources to understand and plan for the changes to MDSAP, ISO 13485, the MDR and IVDR.

ISO 13485:2016

Transition deadline: 28 February 2019

ISO 13485:2016 was published on 1 March 2016 with a three year transition period. After the transition period, manufacturers must be certified to ISO 13485:2016/EN ISO 13485:2016 to continue placing product on the market where ISO 13485 is accepted.

To support manufacturers in their transition, BSI now performs QMS audits only to ISO 13485:2016. Get prepared for your upcoming assessment by using our Transition Toolkit, which provides webinars, white papers, Frequently Asked Questions, and training courses to allow you to prepare more effectively.

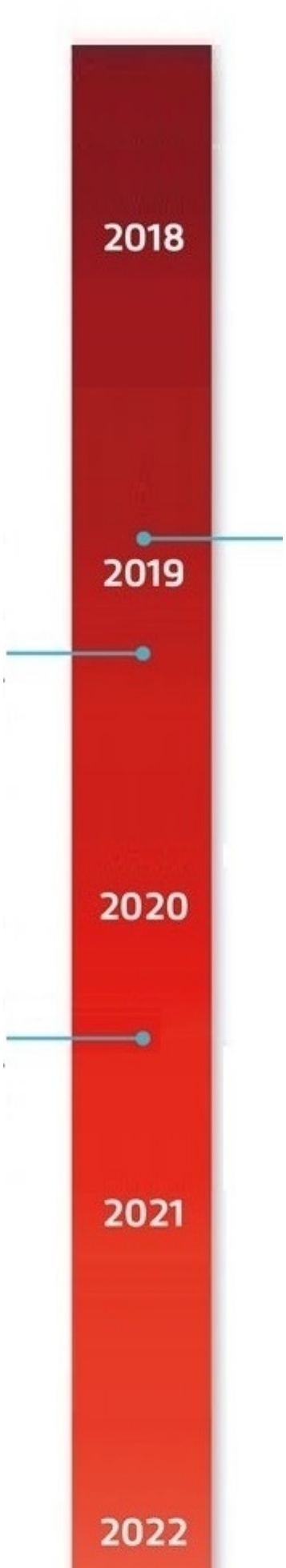
Find our resources on our revision webpage:
bsigroup.com/iso13485revision

MDR

Date of application: 26 May 2020

It's thought that Notified Bodies will begin to be designated to the MDR and IVDR from 2019, but you don't need to wait for us. Prepare your documentation now and make sure you're ready as soon as we're available to assess your products. Early preparation is essential for a smooth transition.

We have a dedicated MDR transition webpage, where we



MDSAP

Deadline: 31 December 2018

The Medical Device Single Audit Program (MDSAP) allows manufacturers to undergo a single audit to the QMS and GMP requirements of a number of Regulatory Authorities, including Australia, Brazil, Canada, Japan and the USA.

Health Canada has announced that it will replace its CMDCAS program with MDSAP from 1 January 2019. Manufacturers wishing to continue selling into Canada will need valid MDSAP certification before this deadline.

Will you sell into Canada after 2019? Visiting our dedicated webpage:
bsigroup.com/mdsap

IVDR

Date of application: 26 May 2022

The five year IVDR transition seems generous, but the time is a reflection of the magnitude of the changes facing IVD manufacturers. You will need to find a Notified Body early if you don't have one already, and it is crucial that you communicate with them about your transition plans so they can accommodate your timelines. You will need a robust strategy to navigate a successful transition.

Familiarize yourself with the changes to device classification and conformity assessment routes, and to the requirements

Do you want to continue receiving our newsletters?

The General Data Protection Regulation (GDPR) is coming on 25 May 2018. It requires organizations to only send emails to those who have requested to hear from them. Re-register with us today to continue receiving our monthly updates.

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