Your partner in progress

Amending Regulation (EU) 2023/607

Frequently asked questions

Will my MDD/AIMDD certificates be renewed, or the dates specified on the certificates changed to extend the validity of the certificates?

The Directives are now void, and hence no changes are allowed to be made to the Directive certificates. The Amending Regulation (EU) 2023/607 allows the MDD/AIMDD certificates to be recognised as valid even beyond the dates indicated on the certificate if certain conditions set out in the Amending Regulation are met, including lodging an MDR application and signing a formal written agreement by certain dates.

My MDD/AIMDD certificates have already expired, and we have an ongoing MDR application with BSI. Can BSI issue the Notified Body confirmation letter ascertaining the receipt of our MDR application?

BSI already has a process in place for issuing confirmation letters to those devices that qualify for it and has issued hundreds of confirmation letters so far to aid manufacturers get market access for their qualifying legacy devices. If you need a confirmation letter for your qualifying legacy devices, please contact your Scheme Manager.

Our Directive certificates are issued by another Notified Body and the MDR application is with BSI. Do we have to continue receiving audits from the Directive Notified Body under appropriate surveillance or can we transfer this to BSI?

The Amending Regulation allows the MDR Notified Body to take over the appropriate surveillance of devices certified under the Directives from the Notified Body that issued the Directive certificates under a tri-partite (transfer) agreement. The transfer of appropriate surveillance to the MDR NB must be completed no later than the 26 September 2024.

BSI worked with other Notified Bodies and EU Authorities to develop **a template for the tri-partite (transfer) agreement**.

BSI has a process in place for transferring the appropriate surveillance of legacy devices. If you intend to transfer the appropriate surveillance of any of your legacy devices certified by another NB to BSI, please contact your BSI Account Manager or Scheme Manager as soon as possible to allow the transfer activities to be completed before the 26 September deadline defined in the (EU) 2023/607 Regulation.

Are manufacturers allowed to make changes to their devices under the Directives for a longer period under the Amending Regulation?

The Amending Regulation does still allow manufacturers to make changes to devices under Directives if such changes do not constitute a significant change in design or intended purpose. While it is possible to make some changes to devices under the MDD/AIMDD, BSI strongly recommends that manufacturers make progress in transitioning their devices to MDR rather than consider making changes under the Directives. Approval of changes under MDD/AIMDD will be strictly limited to those changes that are demonstrated to be essential without which there could be challenges with market availability of safe devices to patients.

BSI had previously issued guidance that submissions must be received by either 1st October 2022 or 1st January 2023 to be assured of meeting the 26 May 2024 deadline. We submitted our files according to these deadlines. What happens to these submissions? Can we now make other submissions in the context of the Amending Regulation extending the transition timelines?

BSI operates on a first-in-first-out basis. Any submissions already received will be placed in the current queue and conformity assessments completed as and when resources (with the appropriate competencies) become available. We strongly recommend that manufacturers do not request to postpone these reviews to ensure timely completion of assessments. Changes to existing submissions could result in delays in scheduling. Any new submissions received will continue to be added to the end of the current queue.

We already have an MDR application with BSI. Is it possible to change my contract from Dedicated service to Standard service for Technical Documentation reviews?

It is possible to change from a Dedicated service to Standard service for Technical Documentation reviews. However, BSI will treat these changed service level reviews as “new” and will issue an “Amendment Agreement to Contract” with a Standard service for the impacted devices only. Such devices moving to the Standard service will be added to the end of the current queue of reviews already in place by that date.

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Will BSI issue new deadlines for submission of Technical Documentation based on the new transition timelines of end of 2027 or 2028?

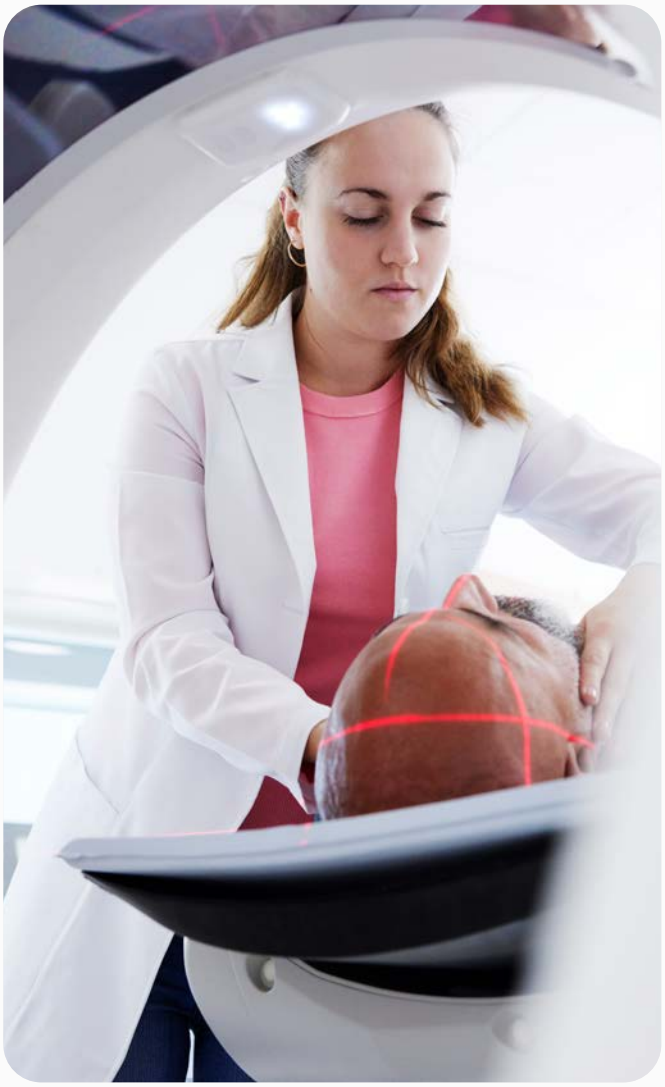
BSI does not intend to issue new deadlines for the submission of the Technical Documentation based on the new transition timelines. It will be the manufacturer's responsibility to ensure that they submit the documentation in a timely manner considering the new MDR transition timelines that will apply to their devices and the usual time required to complete the conformity assessment processes for those types of devices under MDR as published on the **European Commission dashboard** on "Monitoring of availability of medical devices on the EU market". Please consider the need for any external consultation processes for your devices such as medicinal consultations, animal tissue consultations etc., which could extend the conformity assessment processes significantly.

Does BSI anticipate improved capacity as a result of this change?

Since MDR and IVDR were published, BSI has grown 18% CAGR (Compounded Average Growth Rate) every year. BSI continues to adapt its resources plan based on the changes being experienced in the medical device legislations. The Amending Regulation certainly provides additional relief to Notified Bodies in terms of the longer transition timelines. BSI is also constantly working on streamlining its processes and introducing new IT systems to increase efficiency and capacity. BSI will consider new requests in areas where it has capacity available. Please contact the Sales Teams for any enquiries on this matter.

Our MDR certificates have been already issued and we are ready to make changes to the MDR certified devices. Will reviews of changes be deprioritized so that BSI can focus on initial applications only?

All MDR work will be given equal priority. BSI is operating business as usual with any MDR conformity assessment type, including changes, being scheduled as first-in-first-out.



Get in touch

Whether you are starting the certification process, looking to transfer or need to discuss your options, we can guide you through the process.

Request a quote

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