MDR Transition timelines extended FAQs

By Royal Charter

Frequently asked questions

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

A The Directives are now void, and hence no changes are allowed to be made to the Directive certificates. The new Regulation 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 Regulation are met, including lodging an MDR application and signing a formal written agreement by certain dates.

Q Will all the devices covered by my MDD/AIMDD certificates benefit from the longer transition timelines?

A The additional time made available by the new Regulation is aimed at devices transitioning to the MDR. The MDD/AIMDD certificates will be considered valid (for the longer period) only for devices for which there is a signed application and written agreement under MDR with a Notified Body.

Q My MDD/AIMDD certificates have already expired. Will devices covered by these expired certificates benefit from the longer transition timelines? Can I apply to BSI now under MDR to benefit from the longer transition timelines?

A Devices covered by expired MDD/AIMDD certificates (as of the date of publication of the new Regulation) will benefit from the longer transition timelines only if the manufacturer had submitted a signed MDR application and concluded a written agreement with a Notified Body by the expiry date of those certificates, or if the manufacturer has received a derogation/exemption from the Competent Authorities according to Article 59 or Article 97 of MDR. Evidence of derogation/exemption approval may be requested by the Notified Body in such cases.

Q What will the Notified Bodies provide as evidence of the receipt of an MDR application?

A Notified Bodies are working together to develop a template for a confirmation document that will be issued to manufacturers confirming the receipt of an application and signed written agreement under the MDR. The details and the content of the confirmation document are being developed as a collaboration between Notified Bodies.

Q My MDD/AIMDD certificates have already expired, and we have an ongoing MDR application. When can BSI issue the confirmatory document ascertaining the receipt of our MDR application?

A BSI understands the urgency of this matter and we will provide the confirmatory document as soon as the template is finalised, and the steps required to be completed for issuing the document have been completed.

Q My MDD/AIMDD certificates have already expired or are about to expire. We have submitted our MDR application and the conformity assessments are ongoing. Does the new Regulation mean that these expired Directive certificates will have to be maintained and appropriate surveillance carried out or re-started for the expired Directive certificates?

A For the devices transitioning to MDR, the Notified Body is required to continue its appropriate surveillance activities under the Directives until the MDR transition is complete. If such activities had stopped at the point of certificate expiry, these will have to be re-initiated. Changes to the terms and conditions of contract may be required to support appropriate surveillance of devices covered by expired certificates. BSI will provide additional information once the process for this has been finalised.

Q 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?

A The new 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 agreement. Several open questions remain about these provisions in the new Regulation and BSI is working with other Notified Bodies and EU Authorities to resolve these questions and in developing the framework that allows the transfer of appropriate surveillance from the Directive Notified Body to the MDR Notified Body. BSI will allow such transfer of appropriate surveillance from another Notified Body, once these questions are addressed, and a process has been established.

Q Is an MDR application the only condition for benefitting from the longer transition timelines?

A The MDR application is just one of the conditions specified in the new Regulation to benefit from the longer transition timelines. The other conditions are summarised below. Please refer to the Regulation for full details on all the conditions to be met for benefitting from the longer transition timelines. Devices transitioning to MDR may be placed on the market or put into service until the end of 2027 or 2028, based on their classification, only if the following conditions are met:

- those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable
- there are no significant changes in the design or intended purpose

- the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health
- no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9)
- no later than 26 May 2024, the manufacturer or the Authorised Representative has lodged a formal application with a Notified Body in accordance with Section 4.3, first subparagraph, of Annex VII for conformity assessment in respect of a legacy device or in respect of a device intended to substitute that legacy device, and, no later than 26 September 2024, the Notified Body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII

Q Are manufacturer allowed to make changes to their devices under the Directives for a longer period under the new Regulation?

A It is important to remember that the longer transition timelines apply only to devices that are transitioning to MDR. The new 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.

Q BSI had previously issued guidance that submissions must be received by either 1st Oct 2022 or 1st Jan 2023 to be assured of meeting the 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 new Regulation extending the transition timelines?

A 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 after the 1st January 2023 will continue to be added to the end of the current queue.

Q 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?

A It is possible to change from a Dedicated service to Standard service for Techncial Documentation reviews. However, BSI will treat these changed service level reviews as “new” and 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 work already in place by that date.

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

A 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 typical time required to complete the conformity assessment processes for those types of devices under MDR. Please consider the need for any external consultation processes for your devices such as medicinal consultations, animal tissue consultations etc. which could prolong the conformity assessment processes significantly.

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

A Since MDR and IVDR were published, BSI has grown 18% CAGR every year. BSI continues to adapt its resource plan based on the changes being experienced in the medical device legislations. The new 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 be more efficient and release additional capacity. BSI will consider new requests in areas where it has capacity available. Please contact the Sales Teams for any enquiries in this matter.

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

A 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.

DISCLAIMER: Please note, for the MDR timeline, these changes can be considered effective only once published on the Official Journal.

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