# MDR Transition timelines extended FAQs

# MDR 过渡期延长常见问答

By Royal Charter

## Frequently asked questions

## 常见问答

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

**我的 MDD/AIMDD 证书是否会更新，或证书上的有效期是否会变更延长？**

**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.

MDD/AIMDD 指令已失效，因此，不允许对 MDD/AIMDD 证书进行变更。根据新法规，若符合其所列的特定条件（包括提交 MDR 申请和在指定日期前签署正式书面协议等），过期证书仍可被认为有效。

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

**MDD/AIMDD 证书涵盖的所有器械是否均可适用延长的过渡时间表？**

**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.

新法规提供的额外时间主要针对正在申请 MDR 转证的器械。MDD/AIMDD 证书将（在允许延长的时间内）被视为有效，但这仅适用于已经向公告机构提交 MDR 书面申请并与其签署书面协议的器械。

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**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?**

**我的 MDD/AIMDD 证书已过期。这些过期证书涵盖的器械是否可适用延长的过渡时间表？如果我现在向 BSI 提交 MDR 申请，是否可适用延长的过渡时间表？**

**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 maybe requested by the Notified Body in such cases.

过期的 MDD/AIMDD 证书（截至新规发布之日）所涵盖的器械只有在制造商已提交 MDR 申请，并在该证书到期之前已经与公告机构签订书面协议，或者制造商已根据 MDR Article 59 or Article 97 获得主管当局的减免/豁免的情况下，才能适用延长的过渡时间表。在这些情况下，公告机构可要求提供减免/豁免的批准证明。

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**Q** **What will the Notified Bodies provide as evidence of the receipt of an MDR application?**
**公告机构会提供什么文件，来证明已收到 MDR申请?**

**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.
公告机构正在合力制定确认文件的模板，未来将向制造商出具该文件，确认已收到 MDR 申请和签署书面协议。确认文件的相关细节和内容将由公告机构共同协商决定。

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**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?**
**我的 MDD/AIMDD 证书已过期，而我们有一个正在进行的 MDR 申请。BSI 何时可以出具确认性文件，以确认收到了我们的 MDR 申请?**

**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.
BSI 深知其中的紧迫性，一旦最终敲定模板，并完成签发文件所需的执行步骤，我们将立即提供确认性文件。

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**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?**
**我的 MDD/AIMDD 证书已过期或即将过期。我们已经提交 MDR 申请，符合性评审正在进行中。根据新法规，这些过期的指令证书是否仍需维护和重新认证?**

**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.
对于正在申请 MDR 转证的器械，公告机构需要根据指令继续进行监督审核，直至完成 MDR 转证。如果证书过期时停止此类审核，则必须重新启动。为进行对过期证书所涵盖的器械的监督审核，可能需要对合同条款和条件做出变更。最终确定相关流程后，BSI 将及时提供更多信息。

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**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?**
**我们的指令证书由另一公告机构签发，而 MDR 向 BSI 申请。指令证书的监督审核由原公告机构进行，还是可转移由 BSI 进行?**

**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.
根据新法规，如签订三方协议，MDR 公告机构可以从签发指令证书的公告机构处接管进行监督审核。有关新法规的此项规定，仍有几个问题悬而未决。BSI 正在与其他公告机构和欧盟主管当局合作解决这些问题，并制定框架，落实监督审核涉及的公告机构转移。一旦这些问题得到解决，流程得到确立，BSI可以接管其它公告机构签发的指令证书的监督审核。

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**Q** **Is an MDR application the only condition for benefitting from the longer transition timelines?**
**提交 MDR 申请是适用延长过渡时间表的唯一条件吗?**

**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:
根据新法规的规定，MDR 申请只是适用延长过渡时间表的条件之一，其他条件如下。如需详细了解适用延长过渡时间表的所有条件，请参阅法规。只有满足以下条件，正申请 MDR 转证的器械才能在 2027 或 2028 年底前，根据其分类投放市场或投入使用：

- those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable
  继续符合 90/385/EEC 或 93/42/EEC 指令的器械，如适用
- there are no significant changes in the design or intended purpose
  设计或预期用途没有重大变更

- 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

  器械不会对患者、使用者或他人的健康或安全构成不可接受的风险，也不会对公共卫生防护的其它方面构成不可接受的风险

- no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9)

  2024 年 5 月 26 日前，制造商已根据 Article 10(9) 建立质量管理体系

- 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

  2024 年 5 月 26 日前，制造商或授权代表已根据附录 VII 第 4.3条款第一项，向公告机构提出正式申请，要求对遗留器械或拟替代该遗留器械的器械进行符合性评审，并且公告机构和制造商已于2024年9 月 26 日前根据附录 VII 第 4.3 条第二项签署书面协议

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

**根据新法规，制造商能否根据指令对其器械做出变更，以延长有效期?**

**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.

请谨记，延长的过渡时间表仅适用于正在进行 MDR 转证的器械。只要不会构成设计或预期用途的重大变更，新法规仍将允许制造商根据指令对器械做出变更。虽然可以根据 MDD/AIMDD 对器械进行变更，但 BSI 强烈建议制造商推进 MDR 转证，而不是根据指令做出变更。MDD/AIMDD 批准的变更将严格限于必要的变更，即如果不做此类变更，对患者安全的器械市场供应可能会面临挑战。

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**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?**

**BSI 此前曾发布指南，要求必须在 2022 年 10 月 1 日或 2023 年 1 月 1 日之前收到评审材料，以确保赶上 2024 年 5 月的截止期限。我们按照这些截止日期提交了文件。这些文件的进展怎样?现在新法规延长了过渡时间表，我们是否能提交新的文件?**

**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.

BSI 采用先进先出的原则。所有申请材料都将在收到后排到当前的评审列表中，并在资源可用时完成符合性评审。我们强烈建议制造商不要推迟相关评审，以确保及时完成评审。对现有的提交内容做出变更可能会导致日程安排的延后。如果是在 2023 年 1 月 1 日之后提交的新的文件，则将重新排队。

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**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?**

**我们已经向 BSI 提交了MDR 申请。技术文件审核是否可以从专属服务（Dedicated service）变更为标准服务（Standard service）?**

**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.

可以将技术文件评审从专属服务变更为标准服务。然而，BSI 会将变更后的评审视为“新需求”，并签订“补充协议”。变更为标准服务的器械将重新排队等待评审。

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

**BSI 是否会根据 2027 或 2028 年底的新过渡时间表，发布提交技术文件的新截止日期?**

**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.

BSI 不打算根据新的过渡时间表发布提交技术文档的新截止日期。制造商有责任自行推进 MDR 申请，依据最新 MDR 过渡时间表和完成认证的预估时间，及时提交技术文件。如果您的器械需要进行药物咨询和动物组织咨询等，请考虑该外部咨询可能会显著延长认证的周期。

**Q** **Does BSI anticipate improved capacity as a result of this change?**
**面对这一变更，BSI 是否会提高产能？**

**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.

自 MDR 和 IVDR 发布以来，BSI 每年的复合年增长率为 18%。BSI 将继续根据医疗器械法规的变化调整资源计划。就延长的过渡时间表而言，新法规确实为公告机构缓解了更多的压力。BSI 仍在不断简化流程，并引入新的IT系统，旨在提高效率，释放更多产能。如产能允许，BSI 将接收新的申请。如对相关事项有任何疑问，请与销售团队联系。

**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?**
**我们已经取得 MDR 证书，但计划做变更。BSI 是否会下调评审的优先级，以便专注于新申请？**

**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.

所有 MDR 申请都将享有同等的优先级。无论是变更还是其它类型的 MDR 申请，BSI 均会按照先进先出的原则进行。

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