MDR: deadline extension for Class I devices

Article by Miriam Schuh and Selina Stachowitz

The new Medical Device Regulation (Regulation 2017/745) enters into binding effect on 26 May 2020. The MDR contains requirements for the development, manufacture, provision of use information and product surveillance of medical devices which represent far greater hurdles than those which are currently in place under the MDD, AIMD and IVDD. The changes pose new challenges for manufacturers, particularly with regard to the content of technical documentation, clinical evaluations and post-market surveillance. The scale of the new requirements may and often does result in a stricter and therefore longer conformity assessment procedures, meaning a longer time-to-market for new devices.

2. Corrigendum to the MDR
For manufacturers of Class I devices, the 2nd Corrigendum to the MDR, dated 25 November 2019, has brought significant relief.

Instead of the original text of Article 120 (3)
"By way of derogation from Article 5 of this Regulation, a device with a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/42/EEC and which is valid by virtue of paragraph 2 of this Article may only be placed on the market or put into service provided that from the date of application of this Regulation it continues …"

Article 120 (3) will now read as follows:
"By way of derogation from Article 5 of this Regulation, a device which is a class I device pursuant to Directive 93/442/EEC, for which the declaration of conformity was drawn up prior to 26 May 2020 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, or which has a certificate that was issued in accordance with Directive 90/385/EEC or Directive 93/442/EEC and that is valid by virtue of paragraph 2 of this Article, may be placed on the market or put into service until 26 May 2024, provided that from 26 May 2020 it continues …"

In other words, the “hard deadline” of May 2020 will no longer apply, at least for the devices which are explicitly mentioned in Article 120 (3).
Beneficiaries of the deadline extension

Manufacturers of Class I medical devices under the currently applicable MDD whose products would be assigned to a higher class under MDR rules may continue to market their products through 26 May 2024, provided that they are in conformance with the MDD. This applies e.g. for reusable surgically invasive devices classified as Class I (under the new MDR; Annex VIII, 5.2, Rule 6, second bullet point of the MDR), which benefit from the new transitional period provided a declaration of conformity exists for them under the MDD.

Medical apps are classified in accordance with Rule 11 (Annex VIII, 6.3). Accordingly, they are typically classified as Class IIa or higher under the MDR. Manufacturers of medical apps which are presently classified as Class I under MDD/IVDD rules, and which would be assigned to a higher class under MDR rules, will also benefit from the extension.

The deadline extension also benefits manufacturers of devices comprised of substances and generally provides noticeable relief for manufacturers of Class I devices, which face special requirements for the first time under the MDR.

Important: if devices which are marketed under the MDD during the extended transitional period undergo a “significant change” after the MDR takes effect, i.e. a change which could impact the conformity of the device, the change and the device’s conformity are to be assessed under MDR rules, even during the extended transitional period.

Reasons for the extension

According to Germany's Federal Health Ministry, the recently adopted extension is designed in part to address deficiencies relating to notified bodies and ensure equal treatment for manufacturers of Class I devices and manufacturers of high-risk devices.
Conclusion
Regardless of the new transitional periods, the necessary steps to implement the MDR should not be postponed by any means. For one thing, the extended transitional period will end on 26 May 2024. Secondly, Article 120(3) also states that the MDR's requirements relating to post-market surveillance, market surveillance, vigilance, registration of market operators and registration of devices will apply in place of the corresponding requirements in those two Directives; and the deadline for these requirements has not been extended.