

REGULATION ON MEDICAL DEVICES: THE NEWS OF THE MONTH OF JUNE DECRYPTED



This special July edition is dedicated to two publications from June and the EPSCO (Employment, Social Policy, Health and Consumer Affairs) Council of June 14, all of which relate to Regulation (EU) 2017/745 applicable to medical devices. **These publications and events will be deciphered by GMED**, as they should be read carefully, as each word gives important indications on the solutions envisaged to accompany actors in the transition to Regulation (EU) 2017/745 and avoid market supply disruptions.

First, let's recall the **publication by the MDCG** (European Commission Medical Device Coordination Group) of **the position paper MDCG 2022-11** for manufacturers and the **statement issued by the CAMDs** (Competent Authorities for Medical Devices) during their 50th plenary meeting. It is interesting to read these two publications together and decipher them by separating what is almost certain from what remains assumptions for the future.

The common finding of both organizations is:

- The reaffirmation that **no concessions to the safety and performance requirements of the regulation** for medical devices are on the table;

- The **urgency to take measures as soon as possible to avoid any disruption in the supply** of medical devices essential to patient health, given the insufficient pace of transition to the regulation by all manufacturers and the capacity strain on all actors in the certification system, including the notified bodies;
- **The derogation to the placing on the market** provided for in article 59 of the regulation **cannot be the solution** to a break in certification (directive certificate at the end of its validity and regulation certificate not obtained);
- **The solutions to be developed jointly** with all stakeholders should rather **ensure that manufacturers are on the way to compliance with the regulation** than to give additional delays.

The MDCG publication provides additional information, including:

- A reaffirmed commitment **not to change the grace period end date of May 26, 2024, but to develop solutions within the current legal framework;**
- Beyond the capacity constraints of notified bodies, **the need for manufacturers to accelerate their preparation for certification under the regulation** (the rejection rate of applications or incomplete applications lengthening the time and burden of certification is considered far too high) and to submit a complete and compliant application to a notified body at least one year before the expiration of their directive certificate.

The term "complete and compliant application¹" in this last statement deserves clarification. According to an interpretation of the regulation, a complete and compliant application would be an application that includes all the documentation required by the applicable annexes of the regulation and that is accepted by the notified body following the examination of the application in accordance with Article 4.3 of Annex VII.

A final statement in MDCG 2022-11 carries a **hypothetical solution** that the European Commission could use in its legal framework: it is **the use of Article 97 of Chapter VII of Regulation (EU) 2017/745 that deals with market surveillance by competent authorities**. This Article 97 stipulates that in case of non-compliances identified on a medical device by a competent authority during its surveillance activity, but for which no unacceptable risk to the health or safety of patients is present, the authority shall require to put an end to the noncompliance within a reasonable period without requesting the cessation of marketing or even the withdrawal from the market. In the interests of harmonizing the practices of the competent authorities, the Commission may frame this disposition in an implementing act.

¹ For information on how to apply for formal certification with GMED please refer to the [GMED Guide: Application for CE Marking - Regulation \(EU\) 2017/745](#)

Are we to understand that in the event of non-compliance under Article 120 (for example, a directive certificate that is expiring), the use of Article 97 would allow a device to continue to be placed on the market provided that a "complete and compliant application" for certification under the regulation is accepted by a notified body and for a limited period? Of course, this is only conjecture at this point and we will have to wait for more details from the Commission on the use of this Chapter VII cited in MDCG 2022-11.

In addition to these two publications, the Commission provided additional information at **the Council of Europe meeting of Member State Ministers on Employment, Social Policy, Health and Consumers (EPSCO)** on June 14, 2022.

In addition to the situation assessment and the unanimously shared observation, some solutions are put forward by the European Commissioner:

- **Better coordinated surveillance measures;**
- **A change in the frequency of reassessment of notified bodies;**
- **Hybrid audits under regulation (a mix of on-site and remote audits);**
- **Special conditions applicable to legacy devices.**

Even if these measures remain for some very vague and for others, such as hybrid audits, seem to bring little oxygen to the system, several indications converge towards a provision still in connection with Article 97, moreover cited by the German Minister of Health following the intervention of the Commissioner. **Faced with the concerns expressed by many Member States, a situation update must be included again in the next EPSCO scheduled for December 2022.**

Conclusion

In this context and without betting on a "miracle" provision, **GMED remains fully mobilized within the framework of its responsibilities to support all its customers and all manufacturers looking for a notified body in the regulatory certification process.** This includes in particular:

- **An unprecedented development of GMED's capabilities** through the recruitment and qualification of new resources (clinicians, product examiners, auditors, and certification project managers);
- **A search for efficiency in the certification processes** for the benefit of its clients based on feedback from **2 years of practice;**
- **The support of manufacturers via the GMED Training Center** and the **many guides available** to allow everyone to prepare, to file a compliant application, and to obtain as soon as possible a certificate of payment.

GMED is also fully mobilized both at the national level with the various authorities, and at the European level through its **active participation in Team-NB** as a member of the executive board of the association and **in various working groups of the GCDM, to propose relevant solutions to this collective challenge that we must all overcome in the interest of patients.**

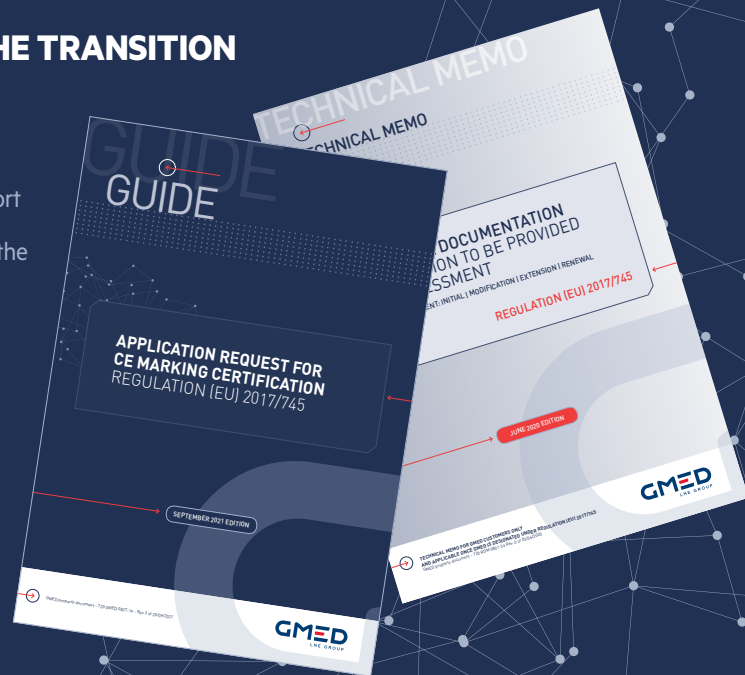


Going the extra mile

WHICH GMED TOOLS ASSIST IN THE TRANSITION TO THE MDR?

- **Dedicated certification project managers** to support you in your projects;
- **Trainings** to acquire the skills needed to implement the European regulation;
- **Publications:** technical guides, technical memos*, newsletters, etc. to set out the expectations of the notified body and the information to be provided as part of an assessment, or updates on regulations or standards;
- **Forums** organized by GMED to bring you the viewpoints of high-caliber experts on key issues for sector stakeholders.

* GMED Technical memos are reserved for the exclusive use of GMED customers.



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