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# TRANSITION TO EUROPEAN MEDICAL DEVICE REGULATION: FEEDBACK AND CHALLENGES TO BE MET

Without providing a full and comprehensive market vision, but based on feedbacks from GMED teams, there is a common denominator at play: heterogeneity in the level of anticipation and preparation of manufacturers for the new Regulation (EU) 2017/745 (MDR).
Only a limited number of market players have sufficiently anticipated this major regulatory, organizational, and financial turning point by implementing a transition plan in accordance with MDR requirements, with the aim of continuing to market their medical devices (MD) in Europe.
Other manufacturers, and there are many of them, have chosen to wait for the end of the grace period to start transitioning to MDR, running the risk of product certification lapse fueling a potential market disruption. Indeed, as certification timelines are longer under the new regulation compared to those under the directive, some applications for certification will not be locked in MDR certification before the end of the grace period.

In order to help you better anticipate and prepare for your transition to the MDR, here is some feedback from GMED teams who have monitored the situation over the past 15 months. Highlighting the points to look out for during the various phases of the certification process under this new regulation.

## A FEEDBACK

### 1. Duration and costs to be anticipated for the transition to the MDR

Apart from feeling that a number of market players are not well prepared for this transition, GMED teams frequently note significant discrepancies between budgets accrued by manufacturers and actual certification costs under the MDR.

It is not so much the hourly/daily cost that varies significantly, but rather the time spent on the regulation certification process. Consequently, manufacturers of class IIa and IIb MDs in particular, realize the duration of technical documentation assessments fast approaching that of class III MDs leading to the significant uptick in cost.

Moreover, the pre-application phase, application review, final verification, decision-making and post-market follow-up are stages clearly set out in the regulation leading to an increase in time and cost of certification projects under MDR.

Finally, manufacturers do not always have a clear understanding of stages involved, assessment time and therefore the duration of projects under the MDR. This has a major impact on the reverse planning needed to market their medical devices.

## 2. Pre-application phase

The pre-application phase allows the manufacturer to specify the projected scope of certification, to inform GMED of the main features of the medical devices, including the classification claimed, and the ways in which the required conformity can be demonstrated. This vital step allows GMED to size the service provision in terms of duration, cost and qualifications required, etc.

If the manufacturer does not grasp MDR requirements, this will be reflected during the pre-application phase with a potentially significant number of exchanges with their NB. Time needed to align with the requirements will automatically impact the assessment schedule and consequently the duration of the certification process for the MD in question.

GMED teams noted the following pitfalls, among other things, while conducting pre-application phase reviews:

- The Single Information Form (SIF) is not signed or is not completed accurately/fully;
- Information relating to the identification of the manufacturer and the sites concerned is inconsistent with official registration data (Kbis (certificate of incorporation extract) and existing certifications;
- Definition of product and technology codes is inaccurate;
- Definition of generic names of devices is not sufficiently precise to meet regulatory requirements in conjunction with product codes or EMDN codes (confusion with the voluntary fields). Discrepancies in the translation are also noted;
- Rationale behind MD status is missing or inaccurate;
- Classification of the MD (especially for software) is incorrect;
- Classification rationale is unsatisfactory, or may turn out to be incomplete due to a lack of information on the device even if the classification is correct;
- Conformity assessment procedure is incompatible with MD class;
- Definition of activities carried out as part of quality management system (QMS) and company's regulatory roles is imprecise;
- Suppliers and subcontractors are poorly identified or the list is not comprehensive. Company name and contact details of suppliers and subcontractors are essential in order to devise the audit program;
- Only some MD features are taken into consideration (e.g.: 2 variants of the MD, etc.);
- The different manufacturing flows are not properly considered or detected during the application review and therefore impact the service provision;
- Identification of process applicability (cleaning, packaging, sterilization, etc.) appropriate for the medical devices in question is inaccurate;
- Validation logics for the relevant MDs are not specified to a sufficient extent (for example: coverage of validations presented in the technical documentation);
- A definition of critical/complex processes inconsistent with the MDT technological codes provided;
- An overly rigorous, minimalist or non-existent approach to the substance concept in terms of the new MDR requirements;
- Readiness and maturity of QMS are insufficient (e.g.: internal audit, management review not carried out) and preferred audit periods are inconsistent with the availability of technical documentation and the time required for a review thereof.

Finally, one of the noteworthy points noted by our teams remains the way in which manufacturer's application and certification projects are organized. All too often we receive Single Information Forms (SIF) including information on an entire product range instead of just on the MDs covered by the application for certification.

Quality and accuracy of information submitted during the pre-application phase are key aspects conditioning the correct identification of the subsequent stages in the certification process.

***Note: GMED teams would like to remind their clients that an FI-INF tab contains definitions and recommendations on how to complete the SIF correctly.***

## 3. The application review phase

During the application review phase, GMED teams analyze and confirm or invalidate data and manufacturer's claims. They will also check the completeness of the application file based on a review of documents submitted by the manufacturer. As far as the NB is concerned, this phase is the first step in the certification process leading to the continuation or suspension of the certification process, or even the rejection of the application for certification.

If the application is refused, the NB is obligated to inform the authorities of the refusal via EUDAMED, stating the reasons why. It is therefore imperative for the manufacturer to take into account the reasons for rejection, blocking, etc. stated by GMED.

In cases where the certification project was accepted, the GMED teams noted on several occasions that the service provision initially offered to the manufacturer at the pre-application phase, was subject to revision with an increase in the number of days for the review based on new elements identified following the application review. The reasons include the following:

- Technical documentation sent by the manufacturer turns out to be incomplete (for example: the manufacturer refers to the technical documentation of other MDs that are not available or not covered by the application). In this context, GMED will not be able to take these data into account;
- The structure of the technical documentation does not meet the requirements of the NB or the structure used is not presented and does not explain the logic for demonstrating the conformity of the MD in question (the document is not searchable, the document is unclear or not readable or multilingual, etc.);
- Technical documentation covers several MDs and the NB cannot identify the specific elements corresponding to the MD covered by the application;
- Documents relating to the QMS (procedures, plans, etc.) are missing;
- Precise reference to the location of the data in the technical documentation is missing: document reference, paragraph concerned as well as applicable annexes, etc.

***Note: Technical memo: Technical Documentation: Information to be provided for assessment - Regulation (EU) 2017/745 is available for GMED customers from their Certification Project Manager.***

## 4. Assessment phases

This phase corresponds to the stage during which NB teams verify the conformity of the medical device, the relevant technical documentation and the manufacturer's quality management system through a series of documentary assessments and audits, etc.

This phase has largely evolved in comparison with the directives relating to MDs.
The more precise requirements of the MDR have significantly impacted the assessment method. The level of expertise required to assess conformity involves a greater number of experts for a given project.

For class IIa and IIb MDs, the core of the assessment was the audit under the old regulation whereas, under the MDR, the core of the assessment is a balance between the technical documentation review and the QMS audit.

Part of the data resulting from the technical documentation review serves as audit input data.

Some challenges have yet to be addressed to ensure the smooth flow and processing of assessment activities:

- Document identification is not always consistent across all technical documentation and leads to a loss of traceability;
- The format of documents is inappropriate. It is sometimes impossible to access the document because it is too large, or to navigate or search using keywords;
- Technical documentation lacks maturity and has not been sufficiently checked/updated: omissions, inaccuracies, inconsistencies between parts of the file;
- Timescales for consulting the competent authorities and groups of experts have not been factored in;
- Content of technical documentation has not been checked: submission of copious raw data without analysis or synopsis, use of inappropriate or unjustified historical data and inadequate clinical data with regard to article 61, etc.

Another sensitive issue that frequently comes to the fore and which can strongly impact the certification project and inherent deadlines: substantial modifications to the MD or QMS.

According to feedbacks from GMED teams, this subject matter alone may warrant a specific strategy on the part of the manufacturer. Indeed, in some cases, manufacturers submit substantial modification projects during the medical device assessment phase, thus impacting the input data taken into account by reviewers. This may well halt the assessment and lead to re-analysis of the entire project: review of the service provision, of the experts involved in the project, or the number of days allocated to the assessment or audit process, etc.

***Note: It is advisable to carefully analyze the impact of such an application during the project assessment cycle accepted by GMED.***

## 5. Decision of the notified body vis-a-vis the certification project

If certification is refused or subject to conditions, the initial strategy behind the manufacturer's project is often redirected. This may impact the MD certification date.

GMED teams generally advise manufacturers to liaise with their NB as quickly as possible to align on the blocking points to be corrected in order to be in a position to continue with the certification project. This usually involves additional assessment(s)/audit(s). Therefore, a thorough understanding of major non-conformities is key to successfully unblocking the situation. Indeed, certification can only be considered if responses to the non-conformity category are deemed satisfactory and the related evidences verified.

***Note: Manufacturers should not hesitate to contact GMED teams for more information and to review European Commission's reference documents, MDCG guides, guides and technical memos[1] published by GMED.***

At this stage, GMED teams have not noted any major post-decision issues.

[1] *GMED Technical memos are reserved for the exclusive use of GMED customers*

The main point to remember is the reality of a longer and more detailed decision and review process under the MDR involving more decision-makers/experts compared to MD guidelines.

Anticipation is therefore one of the main factors for the timely implementation of a certification project.

## Conclusion

Given the large number of applications for certification under MDR, the NBs have, as a general rule, reduced the number of potential reviews per project to allow a reasonable time for decision-making and file closure.

It is essential for manufacturers to factor in the amount of preparation required for their projects/files and to have a sound understanding of the ins and outs of each stage in the certification process (from the preliminary review phase through to decision-making) in order to better predict the time and cost involved in marketing their MDs - a process which is already much lengthier under the MDR.

# Going the extra mile

**WHICH GMED TOOLS ASSIST IN THE TRANSITION TO THE MDR?**

- **The Regulation (EU) 2017/745 Transition Service (RTS)** for an overview of the process, stages and issues involved (available soon);
- **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[2], 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.

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



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