This Frequently Asked Questions (FAQ) aims to provide additional information in the context of the exceptional renewal of the CE quality system approval certificates according to the directives 93/42/EEC and 90/385/CEE proposed by GMED. The information contained in this document is generic information. It must not be considered as recommendation or advice for a given company. It is up to each manufacturer to define its own strategy. GMED cannot be held responsible for any interpretation of the information given in this document in relation to a particular case.

The answers to the questions are based on GMED's practices and interpretations as of the date of publication of this document. They are susceptible of future evolutions.

Please note that a FAQ on the transitional provisions of Regulation (EU) 2017/745 is available on the CAMD website https://www.camd-europe.eu/regulatory/available-now-mdr-ivdr-transitional-faqs/

GLOSSARY

- PMCF : Post-Market Clinical Follow-up
- PMS : Post-Market Surveillance
- PSUR : Periodic Safety Update Report

CONTENTS

I. Eligibility		
1.	**Question**	**Does the exceptional renewal apply to all types of CE certification?**
	Answer	The exceptional renewal only applies to CE quality system conformity certificates: - Annex II (with the exception of point 4), V or VI of Directive 93/42/EEC; - Annex II (with the exception of point 4) and V of Directive 90/385/EEC.
2.	**Question**	**If the re-classification calls for the change from Technical Files to Design Dossiers, and a subsequent review and approval of each by GMED, does the exceptional renewal apply if the classification of devices change?**
	Answer	Based on the interpretation document issued by the CAMD (see page 1), if the reclassification comes from the Regulation classification rules, then the company can apply to an exceptional renewal. The conditions to maintain this “Directive” certificate are detailed in Art 120 of the Regulation. *Note 1: This provision does not apply to the reclassification of Class I devices, devices referred to in Annex XVI of Regulation (EU) 2017/745 and custom-made devices.* *Note 2: A technical documentation which conforms to annexes II and III of the (EU) 2017/745 Regulation is required for any device under the regulation scope in order to claim the compliance with the requirements of the Regulation. Please note that the Regulation does not mention the terms "Technical Files" or "Design File".*

II.	**Impact on the provisions of the certification process**	
3.	**Question**	**What happens if I do not ask for exceptional renewal?**
	Answer	The duration of the CE quality system certificates remains at the current expiry date. If the expiry date is before May 25, 2020, the certificate will be renewed for a period of 3 years (subject to favorable evaluation results). If the expiry date of the certificate is after 25 May 2020, it will be necessary to apply for initial certification in accordance with Regulation (EU) 2017/745 early enough to ensure certification according to the Regulation before the expiry of the “Directive” certificate.
4.	**Question**	**Will CE certification contracts with a deadline after May 26, 2020 be changed?**
	Answer	An amendment to the contract must be signed by the company to take into account the adjustments related to the transitional provisions. If the company does not undertake to sign this contract, the CE certificates relating to the directives cannot be maintained beyond 26 May 2020.
5.	**Question**	**If we request exceptional renewal, will the audit cycle be changed?**
	Answer	The audit execution cycle remains on a 3-year cycle. The current audit cycle of the company is not modified by the exceptional renewal operation. Therefore, there is no longer a direct link between the audit cycle and the end of the validity of the CE certificate relating to the conformity of the quality system.

6.	**Question**	**If we have a renewal audit scheduled for 2019, is it necessary to apply for an exceptional renewal?**
	Answer	The exceptional renewal operation is carried out independently of the current audits cycle. Therefore, if the company wishes to benefit from a certificate valid until May 27, 2024, the exceptional renewal request will have to be made according to the indications given in the mail* and the form, even if the company has an audit renewal program scheduled for 2019. ** Mail sent on December 12, 2018: "European Regulation EU 2017/745 – Transitional Provisions"*
III. Folder contents		
7.	**Question**	**The documentation requested in the exceptional renewal dossier concerns the provisions laid down for the Regulation or the Directive?**
	Answer	This is the documentation describing the provisions for meeting the requirements of Regulation (EU) 2017/745 required by Article 120 §3. This documentation is required to maintain the validity of the "Directive" certificates beyond 26 May 2020. The provisions relating to the post-market surveillance system and vigilance referred to in Article 120 §3 of Regulation (EU) 2017/745 shall apply from 26 May 2020. It is not necessary to implement them before that date.
8.	**Question**	**What is expected in terms of the documentation to be provided: procedures? A description of the procedures?**
	Answer	This is the documentation describing the provisions to meet the requirements of Regulation (EU) 2017/745 required by Article 120 § 3. A checklist will be transmitted with the offer for exceptional renewal.

9.	**Question**	**What is the difference between the two points mentioned in the mail?** • **the documentation on the manufacturer's post-market surveillance system and, where applicable, on the PMCF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92,** • **a description of the procedures in place to keep up to date the post-market surveillance system, and, where applicable, the PMCF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 87 to 92, as well as the undertaking by the manufacturer to apply those procedures,**
	Answer	The 2 points mentioned above come from the content of the application for certification within the framework of Annex IX of Regulation (EU) 2017/745 (§2.1). These are the elements that will have to be implemented to maintain the "Directive" certificates under Article 120 §3 after May 26, 2020. The difference between the two points is the red part.
10.	**Question**	**The mail appears to be mainly asking for the documents relating to vigilance, but Article 92 mentions Article 86 (PSUR) which does not seem to be required at this stage. Can you clarify this point?**
	Answer	Article 120 §3 of Regulation (EU) 2017/745 refers to all topics covered by Chapter VII (Articles 83 to 100), including the post-market surveillance system (PMS), the Post-Market Clinical Follow-up plan and the vigilance. PSUR is indeed an element of the post-market surveillance system. Nevertheless, it is necessary to distinguish what is required by GMED by May 31, 2019 and what the manufacturer is obliged to implement as of May 26, 2020. To date, GMED considers that the PSUR must be available from May 2021 whether or not the manufacturer has made the transition of its certifications to the Regulation. The request is for PMS documentation and procedures, not for PMS data such as PSUR. However, in the transition to the Regulation, the PSUR will be applicable.

11.	**Question**	**The requested elements relating to the post-market surveillance system relate to the requirements of Regulation (EU) 2017/745. Does this mean that the provisions described must be implemented as soon as the exceptional renewal request is made?**
	Answer	The provisions relating to the post-market surveillance system and vigilance referred to in Article 120 §3 of Regulation (EU) 2017/745 shall apply from 26 May 2020. It is not requested to implement them before that date (see question 12).
12.	**Question**	**Why does GMED request the items covered by section 120 in the exceptional renewal when these provisions only apply as of May 26, 2020?**
	Answer	This request from GMED at this date has several objectives: - To ensure that manufacturers are aware of the requirements, as described in Article 120 §3 of Regulation (EU) 2017/745, to maintain their certificates for Directives 90/385 / EEC and 93/42 / EEC after May 26, 2020 - To know at one year of the date of application of the regulation the provisions that the company sets up in order to be ready for May 26, 2020. Indeed, even if they are not yet exclusively applicable, the projects of systematic and pre-established provisions for the post-market surveillance system and vigilance management should be available. - To reduce the risk that after May 26, 2020, manufacturers will have non-compliances on these aspects, which could potentially result in the suspension of a certificate related to the directives. It will be possible to correct an error relating to a reporting timeframe of a vigilance incident but it will be more difficult to implement the provisions of the Regulation as regards the application of a continuous process and proactive update of the clinical evaluation (Post-Market Clinical Follow-up - Annex XIV).

13.	**Question**	**What happens if the documents provided in the exceptional renewal dossier do not fully meet the requirements of the Regulation?**
	Answer	GMED asks companies to provide this documentation in order to carry out a first level review. The results of this review will be communicated to them. The points raised during this review will have to be taken into account in the context of the implementation of the requirements of Regulation (EU) 2017/745. From 26 May 2020, as part of the surveillance audits for maintaining the validity of CE certificates according to the directives, GMED may identify non-conformities on these provisions with regard to the requirements of Regulation (EU) 2017/745.

IV. Deadlines for changes

14.	**Question**	**What is the deadline for submitting significant changes in the design and intended purpose?**
	Answer	There are two aspects to differentiate: 1) The information requirements of the notified body under the Directives persist after 26 May 2020. As a reminder, they cover: - significant changes in the quality system or the range of products covered, - changes in product design that may affect compliance with the essential requirements or conditions prescribed for the use of the product. 2) From May 27, 2020, any significant change in the design or intended purpose of the device must always be notified to GMED. GMED will then have to withdraw the certificate(s) relating to the CE marking under the directive concerned. It is therefore essential for a manufacturer to plan the transition to Regulation (EU) 2017/745 in coherence with the projects of significant change in the design or intended purpose of its devices.

		For reasons of organization of its load plan, GMED requests that the dossiers for any application for significant change of design or intended purpose have to be submitted before May 31, 2019, for an approval under the Directive. GMED will confirm the feasibility of processing the application after the preliminary review. Any request received after May 31, 2019 will be examined on a case-by-case basis.
15.	**Question**	**What is the deadline for submitting significant changes?**
	Answer	If it concerns a change in the design of the product or its intended purpose (as referred to in Article 120 of Regulation (EU) 2017/745), then the application must be submitted before May 31, 2019. Any request received later will be examined on a case-by-case basis. Other changes (eg new clean room) must be processed according to the requirements of the directives that continue to apply as long as the "Directive" certificates are valid. → Due to the probable load plan in the transition period, GMED may need to make selections in customer solicitations. The processing of the dossiers corresponding to the expiring certificates takes priority over the applications for changes.

16.	**Question**	**What is the deadline for submitting product extension applications covered by the CE quality system certification according to directive?**
	Answer	The deadline is March 22, 2020 in order to allow the processing of the dossier and the issuing of the certificate (if the opinion is favorable) before May 26, 2020 the date from which the notified body is no longer authorized to issue a certification decision regarding the Directives. *<u>Note:</u> these are medical devices covered by a certificate according to Annex II (point 4 excluded), V and VI of Directive 93/42 / EEC of the classes:* *- I sterile,* *- I with measuring function,* *- IIa,* *- IIb covered by a certificate Annex II (point 4 excluded),* *- IIb covered by an Annex V certificate where the certificate of conformity relating to Annex III has been issued by a Notified Body other than GMED.*
V. Regulation		
17.	**Question**	**For a Class III device, if a manufacturer only holds:** **- an CE certificate relating to the conformity of the quality management system according to Annex IX (excluding Chapter 2) of Regulation (EU) 2017/745, and** **- an CE design examination certificate in accordance with Annex II.4 to Directive 93/42 / EEC,** **Could the device be put on the market after May 26, 2020?**
	Answer	No. It is not possible to affix the CE marking to a product and place it on the market on the basis of a mix of the CE Directive and the Regulation (see Article 11 of Directive 93/42/EEC and Article 52 of Regulation (EU) 2017/745).

18.	**Question**	**What happens if my quality system certificate is valid until May 27, 2024 and my design review certificate is valid until June 30, 2022?**
	Answer	The product may be placed on the market or put into service in accordance with the provisions of Article 120 of Regulation (EU) 2017/745 until June 30, 2022. Beyond this date, it may not be placed on the market or put into service only if it is certified in accordance with the provisions of the Regulation.
19.	**Question**	**When shall we apply the PMS provisions for Regulation (EU) 2017/745?**
	Answer	Companies have until May 26, 2020 to implement this regulation, which includes post-market surveillance (PMS). But they can already begin to put these provisions in place. After May 26, 2020 even if the company markets products under Directive certificates (Article 120 of the Regulation), the provisions and procedures relating to the PMS according to the Regulation will have to be implemented.

VI. Main deadlines	**Deadline of application** (dossier submitted and order)	**Deadline for completion of the service**
Application for initial management system certification	05/31/2019	Audit before 11/22/2019 (Last day of audit)
Application for extension of products covered by the "Directive" certificate *Note : these are device covered by a certificate in accordance with Annex II (point 4 excluded), V and VI of Directive 93/42 / EEC of the classes:* - *I sterile;* - *I with measuring function;* - *IIa;* - *IIb covered by a certificate Annex II (point 4 excluded);* - *IIb covered by an Annex V certificate where the certificate of conformity relating to Annex III has been issued by a Notified Body other than GMED.*	03/22/2020	04/20/2020 (range extension report)
Application for certification transfer (quality system approval with design examination or type examination)	05/31/2019	11/30/2019 (passage in comité de lecture)
Application for certification transfer (quality system approval only)	09/30/2019	12/31/2019 (passage in comité de lecture)
Design examination / Type examination : initial application, renewal, extension, significant change of product design or intended purpose	05/31/2019	11/30/2019 (passage in comité de lecture)