

## MANUFACTURER'S DECLARATION

Dear All,

following rule 2017/745 art. 120, Medical Devices class I (is not necessary for class I the involvement of a Notify Body) under Directive 93/42 can be marketed until May 2024 if they'll be certificate in a superior classification (class IIa) under Rule 2017/745.

In the meantime on March 2023 the European Parliament amended Article 120 of the MDR 2017/745 with rule 2023/607, as follows:

*paragraph 3 is replaced by the following:*

.....

**3b. Devices for which the conformity assessment procedure pursuant to Directive 93/42/EEC did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, **may be placed on the market or put into service until 31 December 2028. (Class I)****

**3c. Devices referred to in paragraphs 3a and 3b of this Article may be placed on the market or put into service until the dates referred to in those paragraphs only if the following conditions are met:**

**(a) those devices continue to comply with Directive 90/385/EEC or Directive 93/42/EEC, as applicable;**

**(b) there are no significant changes in the design and intended purpose;**

**(c) 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;**

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

**(e) 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 device referred to in paragraph 3a or 3b of this Article or in respect of a device intended to substitute that 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.**

**3d. By way of derogation from paragraph 3 of this Article, the requirements of this Regulation relating to postmarket surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply to devices referred to in paragraphs 3a and 3b of this Article in place of the corresponding requirements in Directives 90/385/EEC and 93/42/EEC**

GELCIDE ESSENTIAL, Class I Medical Device under Directive 93/42, can be placed in the market with a Declaration of Conformity (Dir. 93/42) as it satisfies the above mentioned points of Rule 2023/607 and Italmed has a Quality System responding to Rule 2017/745 that verifies Essential requirements as Annex I, Risk analysis procedure, Post Market Surveillance, market Surveillance, Vigilance.

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