ITALMED

DECLARATION FOR MEDICAL DEVICES CLASS I

We, the undersigned, declare under our sole responsability, that the medical device:

GELCIDE ESSSENTIAL
Medical Device Class I Product code ITD021 I B 1
Ministry of Health Repertoire Number 1936739.
UDI-DI Basic (GMN): 8013805745747ITD021IA14R

has a Declaration of Conformity that comply with the essential requirements of the Council Directive 93/42/CEE June 14, 1993 and its annexes.
In the mean time the Medical Device respond to Article 10 of MDR 2017/745, in fact we have Technical Documentation declared on the Ministry of Health Site, Clinical Evaluation, PMCF, Analysis of Risk, Design Dossier, Labelling, Instruction for use, UDI-DI basic. Our Quality System has Procedures concerning:

- a strategy for regulatory compliance, including compliance with conformity assessment procedures and procedures for management of modifications to the devices covered by the system;
- identification of applicable general safety and performance requirements and exploration of options to address those requirements;
- responsibility of the management;
- resource management, including selection and control of suppliers and sub-contractors;
- risk management;
- clinical evaluation in accordance with Article 61 and Annex XIV, including PMCF;
- product realisation, including planning, design, development, production and service provision;
- verification of the UDI assignments made in accordance with Article 27(3) to all relevant devices and ensuring consistency and validity of information provided in accordance with Article 29;
- setting-up, implementation and maintenance of a post-market surveillance system, in accordance with Article 83;
- handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;
- processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;
- management of corrective and preventive actions and verification of their effectiveness;
- processes for monitoring and measurement of output, data analysis and product improvement.

Responding to Annex IV of MDR 2017/745 the Medical Device has a Declaration of Conformity, and responding to Annex VIII the Medical Device is class I following Chapter III rule 5
(All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active device or which are intended for connection to a class I active device are classified as:
— class IIa if they are intended for short-term use, **except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity, in which case they are classified as class I**.)

Firenze, March, 7th 2022

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Dr. Alessandro Tosetti

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Capitale sociale interamente versato € 10.000,00

ITALMED

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.

Firenze, 24 ottobre 2023

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