

## DECLARATION FOR MEDICAL DEVICES CLASS I

We, the undersigned, declare under our sole responsibility, 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.**)

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p. Italmed srl  
ITALMED srl  
Viale Mazzini, 15  
50132 FIRENZE  
Dr. Alessandro Tosetti

**ITALMED** S.r.l.

Viale Mazzini, 15 - 50132 Firenze - Tel.+39-055-5003124 - Fax +39-055-571031  
www.italmed.net - italmed@italmed.net - P. IVA 04728600489  
C.F. e P.IVA 04728600489 Iscrizione Registro Imprese Firenze n. 04728600489 REA 473852  
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