FAPOMED

FAPOMED - DISPOSITIVOS MÉDICOS, S.A.

EC DECLARATION OF CONFORMITY

Manufacturer: Fapomed – Dispositivos Médicos, S.A. with headquartered in Av. Dr. Ribeiro de Magalhães, 791, 4610-108 Felgueiras.

Medical devices of subcategory:

Sterile Surgical Gowns

Standard; Reinforced; Small surgery; Urology.

Classification: Class I sterile, rule 1, according to annex IX of the Medical Devices Directive 93/42/EEC as amended by Medical Devices Directive 2007/47/EC.

Conformity assessment: According to Annex VII and Annex V (Production Quality Assurance).

Notified body: Slovenian Institute of Quality and Metrology, no. 1304, with address in Mašera – Spasićeva ulica 10 SI-1000 Ljubljana, Slovenia.

EC certificate number: MDD-142.

Declares:

The medical devices referred above fulfill the essential requirements established in Annex I of Medical Devices Directive 93/42/EEC as amended by Medical Devices Directive 2007/47/EC and Decreto-Lei 145/2009 of 17th June, so they do not compromise the clinical state nor the safety of the patients, nor the safety and the health of the users or, eventually, third parties when used in the proper conditions and according with its intended use, considering that the eventual risks associated to the final purposes are acceptable risks considering the benefits to the patients and they are suitable with high level of health and safety protection.

Is it committed:

a) To create and to keep updated a systematic analysis process of the achieved experience in post-production phase, including the requirements of Medical Devices Directive 93/42/EEC of 14th June as amended by Medical Devices Directive 2007/47/EC and Decreto-Lei 145/2009 of 17th June, annex XVI.

b) To develop proper ways for application of any necessary corrective actions, having in mind the nature and the risks related with the product, and to notify the Competent Authority of its incidents, such as:

- Any dysfunction, malfunction or deterioration in the features or functional behavior of the device, as well in any inadequacy, default or insufficient labeling or instructions of use of the device, which might lead or might had lead to death or serious deterioration of patient health state, users or third part;
- Any indirect damage, as in consequence of a wrong medical decision, related to the medical device, when used in accordance with the instructions of use supplied by the manufacturer;

- Any technical or medical reason related with the features or the functional behavior of a device that, for the reasons stated in previous sentences, lead to a corrective safety action in the Portuguese market, including the same type devices produced by the manufacturer

c) To prepare the technical documentation and to keep it updated, including this declaration and attach, keeping it available to the Competent Authority and the Notified Body, for inspection purposes, during five years after the medical device last production date.

Felgueiras, 30th October 2020

By Presidente of Executive Officer,

(Miguel Lopes da Cunha)