MEDIFIT

Mirandola, 27 ottobre 2016

STERILITY DECLARATION

We hereby declare that, based on the results of the tests at the laboratory authorized Crowned Consulting srl (4678-16 and 4679-16 Test reports), the range of products of the family "Veristeril" pouches and rolls, maintain the sterility of the product contained as follows:

STEAM STERILIZATION: 5 years

ETO STERILIZATION: 5 years

The maintenance of sterility requires to preserve the packaged products and sterile, away from direct sources of light and heat, in a dry place and at temperatures between 10 ° C and 40 ° C (recommended).

Medifit S.r.l.

Digitally signed by Iurcu Nicolae
Date: 2019.04.19 14:31:48 EEST
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DECLARATION OF CONFORMITY

Manufacturer: **Address:**	**MEDIFIT s.r.l.** Via Bruino, 72 - 41037 Mirandola (MO) Italy
Medical Device:	**POUCHES AND ROLLS "VeriSteril"**
Classification Annex IX D. *Lgs*. 46/97	**Class I** not sterile

MEDIFIT s.r.l. declares that Medical Devices POUCHES AND ROLLS "VeriSteril" in each different models are conforming to the essential requirements described in annex I of the Medical Devices Directive 93/42/CEE, consolidated with the requirements to 2007/47/EC, and to the applicable standards.

MEDIFIT s.r.l. has developed a post sale surveillance procedure of its medical device according to MEDDEV 2.12/1. "guidelines on post sale surveillance of Medical Devices".

Applicable Directives:

- Medical Devices Directive 93/42/CEE, consolidated with the requirements to 2007/47/EC

Applicable Standards:

European standards	Title
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (EN ISO 11607-1:2009/A1:2014)
EN ISO 13485:2012	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2012)
EN 868-5:2009	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
EN 868-3:2009	Packaging for terminally sterilized medical devices - Part 3: Paper for use in the manufacture of paper bags (specified in EN 868-4) and in the manufacture of pouches and reels (specified in EN 868-5) - Requirements and test methods

MEDIFIT s.r.l. put at the Authority disposal the Technical File with all the documentation required by Annex VII of the Directive 93/42/CEE for five years starting from the last production date of the device.

Mirandola, 08-01-2018

MEDIFIT s.r.l.
CEO
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