

# 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.



Product Service

# CERTIFICATE

No. Q1N 16 06 95628 001

**Holder of Certificate:** Medifit S.r.l.Via Bruino, 72  
41037 Mirandola (Mo)  
ITALY**Facility(ies):**Medifit S.r.l.  
Via Bruino, 72, 41037 Mirandola (Mo), ITALY**Certification Mark:****Scope of Certificate:** Design and development, production and distribution of packaging materials for medical devices to be sterilized**Applied Standard(s):**EN ISO 13485:2012 + AC:2012  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2003 + Cor. 1:2009)  
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:**

ITA273774

**Valid from:**

2016-08-30

**Valid until:**

2019-08-29

**Date,** 2016-08-30

Stefan Preiß

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## DECLARATION OF CONFORMITY

<b>Manufacturer: Address:</b>	<b>MEDIFIT s.r.l.</b> Via Bruino, 72 - 41037 Mirandola (MO) Italy
<b>Medical Device:</b>	<b>POUCHES AND ROLLS "VeriSteril"</b>
<b>Classification Annex IX D. Lgs. 46/97</b>	<b>Class I</b> 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
<b>EN ISO 11607-1:2009</b>	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (EN ISO 11607-1:2009/A1:2014)
<b>EN ISO 13485:2012</b>	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2012)
<b>EN 868-5:2009</b>	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods
<b>EN 868-3:2009</b>	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  
Mario Neri

