MEDIFIT

Certificate of representation

This is to certify that **ECOCHIMIE Ltd.,** Chisinau, Republic of Moldova is the certified agent in the territory of **Moldova** for equipment manufactured by **MEDIFIT SRL Via Chiarini, 1 41037 Mirandola Modena Italy**. This agent is authorized to act as a local representative of **MEDIFIT SRL** and to deal in all matters concerning this equipment in the aforementioned territory, when acting in capacity of representative.

This certificate has been issued and signed by President of **MEDIFIT SRL.** It is dated **September, 01, 2020** and it will remain valid for a period of five years from this date, at which time, it may be extended or terminated by manual agreement of **MEDIFIT SRL** and **ECOCHIMIE Ltd**.

President: Neri Mario

MEDIFIT S.R.L.
Via Chiarini, 1 - 41037 Mirandola (MO) - IT
Phone +39 0535 30 9575 - info@medifit.tech
Cap. Soc. € 10.000,00 i.v. - Reg. Imp. di MO n. 03682240365
REA di Modena n. 408805 - Cod. Fiscale P.IVA 03682240365
VAT IT03682240365

MEDIFIT

Date of issue: **01 September, 2020**

To whom it may concern

CERTIFICATE OF AUTHORISATION:

Distributorship for **MEDIFIT SRL** products.

This is to certify that,

ECOCHIMIE Ltd.
5/1, Cuza Voda str.
2060MD, Chisinau,
Republic of Moldova
Tel/fax +373(22)-52-34-32, 52-34-22
infoecochimie@gmail.com
info@ecochimie.md
www.ecochimie.md

is our authorised distributor for the complete **MEDIFIT SRL** product line.

This company is able to provide competitive and professional sales information, to take parts in tenders and after-sales service of **MEDIFIT SRL** products to their customers in his area and to participate in tenders on behalf of **MEDIFIT SRL.**

President: Mario Neri

MEDIFIT S.R.L.
Via Chiarini, 1 - 41037 Mirandola (MO) - IT
Phone +39 0535 1814919 - +39 0535 3019575 - info@medifit.tech
Cap. Soc. € 10.000,00 i.v. - Iscr. Reg. Imp. di MO n. 03682240365
REA di Modena n. 408865 - Cod. Fiscale P.IVA 03682240365
VAT IT03682240365

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
Mario Neri

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.

MEDIFIT S.r.l. - Via Bruino 72, 41037 Mirandola (MO)
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P.IVA: 03682240365 C.F. 03682240365 Cap. Soc. € 10.000

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 095628 0002 Rev. 00

Holder of Certificate: MEDIFIT

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:

tuv-sud.com/ps-cert

Scope of Certificate:

Design and development, production and distribution of packaging materials for medical devices to be sterilized

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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.: ITA1065120

Valid from: 2019-01-02
Valid until: 2022-01-01

Date, 2018-10-11

Stefan Preiß

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

ZERTIFIKAT ◆ 認証書 ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Italia

CERTIFICATO

Nr 50 100 6085/2 Rev. 01

Collegato al certificato titolare n° 50 100 6085 (ultima revisione applicabile)
Il presente documento è subordinato alla validità del certificato titolare sopraccitato

Connected to main certificate n° 50 100 6085 (last version)
The present document is subject to the validity of the above-mentioned main certificate

Si attesta che / *This is to certify that*
Si attesta che / *This is to certify that*

IL SISTEMA QUALITÀ DI
THE QUALITY SYSTEM OF

MEDIFIT S.r.l.

SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE:

VIA BRUINO 72 I-41037 MIRANDOLA (MO)

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2015

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE

Gestione della progettazione/sviluppo, gestione della produzione e distribuzione di materiale per il confezionamento di dispositivi medici da sterilizzare (IAF 14)

Management of design/development, management of production and distribution of packaging materials for medical devices to be sterilized (IAF 14)

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 049A

Membro degli Accordi di Mutuo Riconoscimento
EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual
Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Validità / *Validity*
Dal / From: **2018-09-10**
Al / To: **2021-09-09**

Andrea Coscia
Direttore Divisione Business Assurance

Data emissione / *Printing Date*
2018-09-10

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2004-03-02
DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE: 2018-07-07 / EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: 2018-07-07

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"

"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"