M & G PRODUCTS CO., LTD.
NO. 55 SOUTH GANGDONG ROAD YANGZHONG JIANGSU CHINA

AUTHORIZATION LETTER

TRIUMF MOTIV SRL
193 OF 1301 GRENOBLE STR.
CHISINAU CITY, MD 2043 REPUBLIC OF MOLDOVA

Is authorized as licence holder to register, import and sale the following products which are manufactured by:

M & G PRODUCTS CO., LTD.
ADDRESS: NO. 55 SOUTH GANGDONG ROAD YANGZHONG JIANGSU CHINA

Products: All references of product that it wants to registration
-STERILE HEAT-SEALING FLAT REEL
-STERILE SELF-SEALING POUCH
-BD TEST PACK
-PLASMA INDICATOR CARD
-CREPE PAPER
-STEAM INDICATOR CARD
-WRAPPING NONWOVEN

This letter is valid until: Jul. 2022

Jul.25,2019
Signed and date

Digitally signed by Jighili Tatiana
Date: 2021.09.23 16:36:15 EEST
Reason: MoldSign Signature
Location: Moldova

TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60148986 0001

Report No.: 15080731 008

Manufacturer:

M & G Products Co., Ltd.
No. 55 South Gangdong Road
Yangzhong City
212200 Jiangsu
P.R. China

Products:

Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60128382 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

M & G PRODUCTS CO., LTD.

EC DECLARATION OF CONFORMITY

Name and address of the manufacturer: **M & G Products Co., Ltd.**
No. 55 South Gangdong Road, Yangzhong, Jiangsu, China

We declare under our sole responsibility that

the medical device: **Sterilization reel and pouch**

of class: **I**

according to annex IX of directive 93/42/EEC European Directive (and further modifications and integrations-ref.: 2007/47/CE European directive).

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the “final inspection report” of the device. /

The device is sold in non-sterile packaging

Conformity assessment procedure: / **Directive 93/42/EEC Annex V,**

EC-representative name: Caretechion GmbH
EC-representative address: Niederrheinstr. 71, 40474 Düsseldorf, Deutschland Germany
Tel:0211 300 366 18 Fax:0211 300 366 19

Notified Body: /

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197

__Yangzhong MAY.5,2020_____ ___General Manager_____
Place, date Name and function

M & G PRODUCTS CO., LTD.

DECLARATION

We hereby state that the shelf life of the reels from the date of production is 3 years.
And the shelf life after the sterilization of products in the bags is 1 year.

M & G PRODUCTS CO., LTD.
MAR.30,2021

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

M & G Products Co., Ltd.
No. 55 South Gangdong Road
Yangzhong City
212200 Jiangsu
China

has established and applies a quality management system for medical devices for the following scope:

Manufacture and Distribution of Medical Devices

(see attachment for products included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-06-29
Certificate Registration No.:	SX 60128383 0001
An audit was performed. Report No.:	15080731 004
This Certificate is valid until:	2021-06-12

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH
TÜVRheinland
Zertifizierungsstelle

X. Ren

Date 2018-06-29

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
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