

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

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## **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

Signed and date Jul.25,2019



**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\_\_\_\_\_  
Place, date

\_\_\_\_General Manager\_\_\_\_\_  
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



# 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



Date 2018-06-29



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
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