



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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