EC Certificate

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

Registration No.: DD 60128382 0001

Report No.: 15080731 004

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

Products:
Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60101923 0001

Expiry Date: 2020-06-12

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.

Notified Body

Effective Date: 2018-06-29

Date: 2018-06-29

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Digitally signed by Jighili Tatiana
Date: 2020.12.10 14:34:07 EET
Reason: MoldSign Signature
Location: Moldova

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

Date 2018-06-29

X. Ren

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