

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.

Effective Date: 2018-06-29

Date: 2018-06-29

Notified Body



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.

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



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