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EC Certificate

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

Registration No.: DD 60125683 0001

Report No.: 15053823 008

Manufacturer:
CITOTEST LABWARE
MANUFACTURING CO., LTD
No. 48, Xinxiu Road
Haimen City, Jiangsu 226100
China

Products: Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60100201 0001

Expiry Date: 2022-10-23

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: 2017-12-15

Date: 2017-12-15

Notified Body

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.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60125683 0001
Report No.: 15053823 008

Manufacturer:
CITOTEST LABWARE MANUFACTURING CO., LTD
No. 48, Xinxiu Road
Haimen City, Jiangsu 226100
China

Products:

- Collection Swabs
- Blood Lancets
- Scalpel Blades
- Insulin Pen Needles
- Cervical Brushes
- Cervical Scrapers

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Cotton Swabs
- Wooden Tongue Depressors
- Vaginal Speculums

Notified Body

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

X. Ren

Date: 2017-12-14