

EC Certificate



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

Registration No.: DD 2029176-1

Manufacturer: CITOTEST Labware Manufacturing Co., Ltd.
No.339 Beihai West Road,
Haimen,
226100 Jiangsu
P.R. China

Products: Collection Swabs, Blood Lancets, Scalpel Blades, 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

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.

Report No.: 15053823 013
Effective date: 2021-03-16
Expiry date: 2022-10-23
Issue date: 2021-03-16



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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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No.339 Beihai West Road,
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226100 Jiangsu
P.R. China

The scope of certification includes the following manufacturing sites:

No.	Location	Product groups manufactured
/01	CITOTEST Labware Manufacturing Co., Ltd. No.48, Xinxiu Road, Haimen City, 226100 Jiangsu P.R. China	Collection Swabs, Cotton Swabs, Cervical Brushes

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