

EC Certificate



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

Registration No.: DD 2131602-1

Manufacturer: Miraclean Technology Co., Ltd.
Room 301, Building A, No. 18,
Rongshuxia Industrial Zone, Tongxin
Community, Baolong Street, Longgang District,
Shenzhen,
518116 Guangdong
P.R. China

Products: Aspects of manufacture concerned with securing and maintaining sterile conditions:
- Sterile Disposable Sampling Swabs
- Sterile Disposable Medical Swabs

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.

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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.