

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

Registration No.: DD 60126640 0001

Report No.: 17062799 002

Manufacturer: Miraclean Technology Co., Ltd.
No. 18, Rongshuxia industrial Zone
Tongle Community, Longgang District
Shenzhen
518116 Guangdong
China

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

Expiry Date: 2023-03-11

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: 2018-03-22

Date: 2018-03-22

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.