

EC Certificate

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

Registration No.: DD 1743273-1

Manufacturer: NISSHA MEDICAL TECHNOLOGIES SAS
Z.A. des Boutries
12 rue des Cayennes
78700 Conflans Sainte Honorine
France

Products: Non-sterile endoscopy tubing kits

Replaces EC Certificate number DD 1743273-1 dated 2020-07-28

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.