EC Certificate

TÜVRheinland®

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, Registration No.: DD 60109992 0001

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.