EC Certificate

TÜVRheinland®

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

Registration No.: DD 1736638-1

Manufacturer: Robert Helwig GmbH
Zum Technologiepark 6
15711 Königs Wusterhausen
Germany

Products:
- Non-sterile injection cannulae
- Non-sterile irrigation cannulae
- Non-sterile suction cannulae

Replaces Certificate, Registration No.: DD 60142992 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.