

EC Certificate

Product Quality Assurance
Directive 93/42/EEC on Medical Devices, Annex VI

Registration No.: ED 1137104-1

Manufacturer: Linde Gas Therapeutics Benelux B.V.
De Keten 7
5651 GJ Eindhoven
Netherlands

Products: - Liquid nitrogen for cryotherapy, cryopreservation and cryo-surgery
- Carbon dioxide for cryotherapy, endoscopic applications
and cryosurgery

The Notified Body hereby declares that the requirements of Annex VI 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 VI, section 4 of the aforementioned directive. For placing on the market of class IIb 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.