

EC Certificate



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

Registration No.: DD 1040862-1

Manufacturer: SPM Medicare Pvt. Ltd.
B-40, Phase-II, Noida
Gautam Budh Nagar, Uttar Pradesh 201305
India

Products: Sterile insulin syringes with needle for single use
Sterile IV Cannula for single use
Sterile IV Infusion Set for single use
Sterile measured volume Set (Burette Set) for single use
Sterile extension line for single use

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.



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