TÜVRheinland®

EC Certificate

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

Registration No.:	DD 2319673-1
Manufacturer:	Shandong Qinkai Medical Industry Co., Ltd. (South Section of Quancheng Road in Industrial Park) Medical Equipment Industrial Park, Chengwu County, Heze, 274200 Shandong, P.R. China
Products:	Disposable Infusion Sets, Disposable Syringes with Needles, Disposable Blood Transfusion Sets, Disposable Burette Infusion Sets, Scalp Vein Sets For the following medical devices the scope covers the aspects of manufacture concerned with securing and maintaining sterile conditions: Urine Bags, Surgical Face Masks

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.