EC Certificate

TÜVRheinland®

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.:	HD 1582538-1
Manufacturer:	Microtech Medical (Hangzhou) Co., Ltd. No.108 Liuze St., Cangqian, Yuhang District, Hangzhou, 311121 Zhejiang P.R. China
Products:	Ambulatory Insulin Infusion Pumps, Insulin Infusion Pump Reservoirs, Insulin Infusion Sets, Continuous Glucose Monitoring Systems

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 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.