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EC Certificate

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

Registration No.: DD 60132408 0001

Report No.: 15094928 006

Manufacturer:
Tianjin Huahong Technology
Co., Ltd.
A01, Plant B
No. 278, Hangkong Road, Tianjin Pilot Free
Trade Zone (Air Port Industrial Park)
300308 Tianjin
China

Products: Sterile Lancets, Insulin Pen Needles

Replaces Approval, Registration No.: DD 60119951 0001

Expiry Date: 2023-08-24

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.

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Herbert Zhong

Effective Date: 2018-12-20

Date: 2018-12-20

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.