EC Certificate

TÜVRheinland®

Production Quality Assurance
MDD Annex V

Registration No.:	DD 2091024-1
Manufacturer:	Promisemed Hangzhou Meditech Co., Ltd. No. 1388 Cangxing Street, Cangqian Community, Yuhang District, Hangzhou City 311121 Zhejiang P.R. China
Products:	Insulin Pen Needles, Blood Lancets, Safety Lancets, Heel Blood Lancets, Insulin Syringes, Safety Insulin Syringes; For following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions: Intubating Stylets Replaces Approval, Registration No.: DD 60141157 0001

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.

Report No.:	15063511 021
Effective date:	2020-11-17
Expiry date:	2023-10-22
Issue date:	2020-11-17

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Herbert Zhong
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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