

# EC Certificate



## 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.

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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.