

**EC Declaration of Conformity**  
符合性声明



Name and address of the manufacturer:

Promisemed Hangzhou Meditech Co., Ltd.  
No. 1388 Cangxing Street, Cangqian Community, Yuhang  
District, Hangzhou City, 311121 Zhejiang, China

Name and address of the European  
Authorized Representative:

Medical Technology Promedt Consulting GmbH  
Altenhofstrasse 80, 66386 St. Ingbert, Germany.  
Tel: +49(0) 6894 581020  
fax: +49(0) 6894 581021  
e-mail: info@mt-procons.com

We declare under our sole responsibility that  
the medical device:

**Insulin Pen Needles**

UMDNS-code:

**18071**

UMDNS description (Device group):

**Syringes, Insulin, Shielded-Needle**

Ordinary type: IPN-34-3.5, IPN-34-4, IPN-34-5, IPN-33-4, IPN-33-5, IPN-33-6, IPN-32-4, IPN-32-5, IPN-32-6, IPN-32-8, IPN-31-4, IPN-31-5, IPN-31-6, IPN-31-8, IPN-31-10, IPN-31-12, IPN-30-5, IPN-30-6, IPN-30-8, IPN-30-10, IPN-30-12, IPN-29-5, IPN-29-6, IPN-29-8, IPN-29-10, IPN-29-12.

Product specification:

Safety type: SPN-29-4, SPN-29-5, SPN-29-6, SPN-29-8, SPN-30-4, SPN-30-5, SPN-30-6, SPN-30-8, SPN-31-4, SPN-31-5, SPN-31-6, SPN-31-8.

Dual safety type: DPN-29-4, DPN-29-5, DPN-29-6, DPN-29-8, DPN-30-4, DPN-30-5, DPN-30-6, DPN-30-8, DPN-31-4, DPN-31-5, DPN-31-6, DPN-31-8.

of class:

**Ila.**

according to annex IX of directive 93/42/EEC: **Rule 6**

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Conformity assessment procedure:

**Directive 93/42/EEC Annex V.**

Registration no.:

**DD 2091024-1**

Issue date:

**2020-11-17**

Expiry date:

**2023-10-22**

Name and address of the Notified Body:

**TÜV Rheinland LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg, Deutschland, Germany.**

Notified body number :

**0197**

*Hangzhou, 2020.11.2*  
\_\_\_\_\_  
Place and date

*Zearou Yang / RA*  
\_\_\_\_\_  
Name and function  
Zearou YANG /Regulatory Affairs Manager