

# EC Declaration of Conformity



No. 2021072301

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: OBELIS S.A  
Bd. Général Wahis, 531030 Brussels, Belgium.  
Tel: +32 27325954, Fax: +32 27326003  
E-mail: mail@obelis.net

We declare under our sole responsibility that the medical device:

**Insulin Pen Needles**

Intended use:

It is intended for subcutaneous injection of insulin in the treatment of diabetes.

Basic UDI-DI code:

697122740IPNPZ

UMDNS-code:

18071

UMDNS description (Device group):

Syringes, Insulin, Shielded-Needle

Product type/specification:

**Insulin Pen Needles:**

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.

of class:

Ila

according to annex VIII of Regulation (EU) 2017/745 :

Rule 6

meets the provisions of the Regulation (EU) 2017/745 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:

Annex IX, chapter I & III+ TD section 4.

Standards applied:

Applied standards are listed in the GSPR Checklist

Registration no.:

HZ 2091024-1

Issue date:

2021-07-22

Expiry date:

2025-11-13

Name and address of the Notified Body:

TÜV Rheinland LGA Products GmbH

Tillystraße 2, 90431 Nürnberg, Deutschland, Germany.

Notified body number :

0197

Design examination certificate:

NA

Date of DoC validity:

2021-07-23

Hangzhou, 2021.07.23  
Place and date

Zearou Yang / RA  
Name and function (signature)  
Zearou YANG /Regulatory Affairs Manager