EC Declaration of Conformity

Promisemed®

No. 20210723CE

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:	**Safety Insulin Pen Needles**
Intended use:	**It is intended for subcutaneous injection of insulin in the treatment of diabetes.**
UDI-DI:	**697122740SPNRK**
UMDNS-code:	**18071**
UMDNS description (Device group):	**Syringes, Insulin, Shielded-Needle**
Product type/specification:	**Safety Pen Needles:** 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.
of class:	**IIa**
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 exmination certificate:	**NA**
Date of DoC validity:	**2021-07-23**

Hangzhou 2021.07.23

Place and date

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