

EC Declaration of Conformity



No. 2022031806

Name and address of the manufacturer: Promisemed Hangzhou Meditech Co., Ltd.
No. 1388 Cangxing Street, Cangqian Community, Yuhang District, Hangzhou City, 311121 Zhejiang, China.

SRN of the manufacturer: CN-MF-000008465

Name and address of the European Authorized Representative: OBELIS S.A
Bd. Général Wahis, 53, 1030 Brussels, Belgium.
Tel: +32 27325954, Fax: +32 27326003
E-mail: mail@obelis.net

SRN of the European Authorized Representative: BE-AR-000000106

Name and address of the Swiss Authorized Representative: OBELIS SWISS GmbH
Ruessenstrasse 12, 6340 Baar/ZG, Switzerland

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: **alphacheck professional Pen-Needle PLUS:**
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: **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: **2022-03-18**

Hengzhou 2022.03.18
Place and date

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