

EU Declaration of Conformity



No. 2025112010501

Name and address of the manufacturer:

Promisemed Hangzhou Meditech Co., Ltd.

No. 1388 Cangxing Street, Cangqian Community, Yuhang District, Hangzhou City, 311121 Zhejiang, P.R. 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.

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 issuing the EU DOC for the medical device:

Safety Insulin Pen Needles

Intended use:

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

Basic UDI-DI code:

697122740SPNRK

EMDN Code:

A010101

Product model/type/specification:

Alphacheck 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,

SPN-32-4, SPN-32-5, SPN-32-6, SPN-32-8.

of class:

Ila

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

Rule 6

To which this declaration relates is in conformity with the requirements of the Regulation (EU) 2017/745 that apply to it.

References to the relevant common specification/harmonised standards used:

- EN 556-1:2024;
- EN ISO 15223-1:2021;
- EN ISO 10993-10:2023;
- EN ISO 10993-12:2021;
- EN ISO 10993-18:2020;
- EN ISO 10993-18:2020/A1:2023;
- EN ISO 10993-23:2021;
- EN ISO 11135:2014;
- EN ISO 11135:2014/A1:2019;
- EN ISO 11607-1:2020;
- EN ISO 11607-1:2020/A1:2023;
- EN ISO 11607-2:2020;
- EN ISO 11607-2:2020/A1:2023;
- EN ISO 11737-1:2018;
- EN ISO 11737-1:2018/A1:2021;
- EN ISO 11737-2:2020;
- EN ISO 13485:2016;
- EN ISO 13485:2016/AC:2018;
- EN ISO 13485:2016/A11:2021;
- EN ISO 14971:2019;
- EN ISO 14971:2019/A11:2021.

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Name and address of the notified body:

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

Notified body number:

0197

Conformity assessment procedure:

Annex IX Chapter I, Section 2 and 3 and Chapter III.

Certificate number:

HZ 2091024-1

Hangzhou, 2025-11-20

Place, date of issue (YYYY-MM-DD)

A handwritten signature in black ink, appearing to read "杨瑞清" (Yang Ruiqing).

数字签名者: Zearou Yang
日期: 2025.11.21
11:51:59 +08'00'

Name, function (signature)

Zearou YANG, Person responsible for regulatory compliance