

EC Declaration of Conformity



No. 2023080910501

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

**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.

Basic UDI-DI code:

697122740SPNRK

EMDN Code:

A010101

Product model/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,
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

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.

Union harmonisation legislation:

Not available

**References to the relevant
specification/harmonised standards used:**

- | | |
|-------------------------------|------------------------------|
| - EN ISO 10993-12:2021 | - EN ISO 13485:2016/A11:2021 |
| - EN ISO 10993-23:2021 | - EN ISO 13485:2016/AC:2018 |
| - EN ISO 11135:2014/A1:2019 | - EN ISO 14971:2019/A11:2021 |
| - EN ISO 11737-1:2018/A1:2021 | - EN ISO 15223-1:2021 |
| - EN ISO 11737-2:2020 | |

Name and address of the notified body:

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

Notified body number :

0197

Conformity assessment procedure:

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

Certificate number:

HZ 2091024-1

Hangzhou, 2023-08-09

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

Name and function (signature)

Zearou YANG, Person responsible for regulatory compliance