# EU Declaration of Conformity

**No.** 2025112011101

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| **Name and address of the manufacturer:** | Promisemed Hangzhou Meditech Co., Ltd.<br>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<br>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<br>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 Dual Safety Pen Needles:<br>Type D:<br>DPN-29-4, DPN-29-5, DPN-29-6, DPN-29-8,<br>DPN-30-4, DPN-30-5, DPN-30-6, DPN-30-8,<br>DPN-31-4, DPN-31-5, DPN-31-6, DPN-31-8.<br>DPN-32-4, DPN-32-5, DPN-32-6, DPN-32-8. |
| **of class:** | IIa |
| **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 11607-2:2020;
- 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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| | - EN ISO 11607-1:2020/A1:2023; |
| **Name and address of the notified body:** | TÜV Rheinland LGA Products GmbH<br>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)*

数字签名者：Zearou Yang
日期：2025.11.21
11:53:05 +08'00'

**Name, function** *(signature)*

*Zearou YANG, Person responsible for regulatory compliance*