EC Declaration of Conformity

No. 2022090310402

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**
We declare under our sole responsibility that the medical device:	**Safety Blood Lancets**
Intended use:	**It is intended to be used by a healthcare provider or patient self to manually puncture the skin of a patient to obtain a small blood specimen.**
Basic UDI-DI code:	**697122740SLTRK**
EMDN Code:	**V010401**
Product type/specification:	**Safety Blood Lancets:** **SL-21-12T, SL-21-18T, SL-21-20T, SL-21-22T, SL-21-24T, SL-21-28T, SL-23-18T, SL-26-18T, SL-28-15T, SL-28-16T, SL-28-18T, SL-28-20T, SL-30-15T, SL-30-16T, SL-30-18T, SL-30-22T.**
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.**
References to CS	**Not available**
Certificate Number:	**HZ 2091024-1**
Issue date:	**2022-09-02**
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:	**Not available**

EC Declaration of Conformity	Promisemed®

Date of DoC validity: **2022-09-03**

Hangzhou, 2022-09-03
Place and date *(YYYY-MM-DD)*

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