EC Declaration of Conformity

Promisemed®

No. 20210723

Name and address of the manufacturer:	**Promisemed Hangzhou Meditech Co., Ltd.** **No. 1388 Cangxing Street, Cangqian Community, Yuhang District, Hangzhou City, 311121 Zhejiang, China.**
Name and address of the European Authorized Representative:	**OBELIS S.A** **Bd. Général Wahis, 531030 Brussels,Belgium.** **Tel: +32 27325954, Fax: +32 27326003** **E-mail: mail@obelis.net**
We declare under our sole responsibility that the medical device:	**Blood Lancets**
Intended use:	**It is intended for manually puncture the skin of a patient to obtain a small blood specimen.**
Basci UDI-DI code:	**697122740BLX9**
UMDNS-code:	**10440**
UMDNS description (Device group):	**Lancets, Blood**
Product type/specification:	**Blood Lancets:** **BL-21G, BL-23G, BL-26G, BL-28G, BL-30G, BL-32G, BL-33G**
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.**
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 exmination certificate:	**NA**
Date of DoC validity:	**2021-07-23**

Hangzhou, 2021.07.23
Place and date

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