

EC Declaration of Conformity



No. 2022031802

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

Name and address of the Swiss Authorized Representative: OBELIS SWISS GmbH
Ruessenstrasse 12, 6340 Baar/ZG, Switzerland

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: alphacheck soft 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

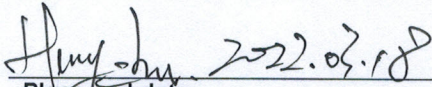
Expiry date: 2025-11-13

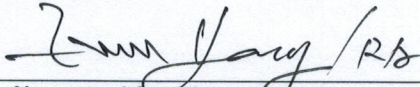
Name and address of the Notified Body: TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431 Nürnberg, Deutschland, Germany.

Notified body number : 0197

Design examination certificate: NA

Date of DoC validity: 2022-03-18


Place and date


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