# EC Declaration of Conformity

Promisemed®

No. 20220318-02

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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, 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.**<br>**Tel: +32 27325954, Fax: +32 27326003**<br>**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**<br>**Ruessenstrasse 12, 6340**<br>**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:**<br>**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.

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| 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**<br>**Tillystraße 2, 90431 Nürnberg, Deutschland, Germany.** |
| Notified body number : | **0197** |
| Design exmination certificate: | **NA** |
| Date of DoC validity: | **2022-03-18** |

2022.03.18

**Place and date**

Zearou Yang /RA

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