EC Declaration of Conformity

No. 2023080910901

Name and address of the manufacturer:	Promisemed Hangzhou Meditech Co., Ltd. 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 Bd. Général Wahis, 53, 1030 Brussels, Belgium.
SRN of the European authorized representative:	BE-AR-000000106
We declare under our sole responsibility that the medical device:	Heel Blood Lancets
Intended use:	It is intended for heel blood collection of the premature or newborn.
Basic UDI-DI code:	697122740HBX7
EMDN Code:	V010401
Product model/type/specification:	Heel Blood Lancets: HB-065, HB-085, HB-100, HB-150.
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.

Union harmonisation legislation:	Not available
References to the relevant specification/harmonised standards used:	- EN ISO 10993-12:2021 - EN ISO 10993-23:2021 - EN ISO 11135:2014/A1:2019 - EN ISO 11737-1:2018/A1:2021 - EN ISO 11737-2:2020 - EN ISO 13485:2016/A11:2021 - EN ISO 13485:2016/AC:2018 - EN ISO 14971:2019/A11:2021 - EN ISO 15223-1:2021
Name and address of the notified body:	TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg, Deutschland, Germany.
Notified body number :	0197
Conformity assessment procedure:	Annex IX, chapter I & III+ TD section 4.
Certificate number:	HZ 2091024-1

Hangzhou, 2023-08-09

Place and date of issue *(YYYY-MM-DD)*

Name and function *(signature)*

Zearou YANG, Person responsible for regulatory compliance