EU Declaration of conformity

Of

Safety Lancet

File number: HH-JS-TF-002-05

Revision A/5

Effective 2025-10-30

Documents Revision History

Signature	Date	Rev.	Description
Bingjie Chen	2022-01-27	A/0	Add documentation according to MDR
Ningning Wang	2023-04-21	A/1	Update the declaration of conformity title
Ningning Wang	2023-07-26	A/2	Update the Conformity assessment
Ningning Wang	2024-01-15	A/3	Add alternate manufacturing site
Ningning Wang	2024-03-15	A/4	Add new models and specifications
Ningning Wang	2025-03-14	A/5	Add new models and manufacturing locations

EU DECLARATION OF CONFORMITY

Name of the manufacturer:	**Tianjin Huahong Technology Co., Ltd.**
Registered Place of Business:	**A01, Plant B, No.278, Hangkong Road,Tianjin Pilot Free Trade Zone (Air Port Industrial Park), 300308 Tianjin, China**
Manufacturing Address:	**A01, Plant B, No.278, Hangkong Road,Tianjin Pilot Free Trade Zone (Air Port Industrial Park), 300308 Tianjin, China** **1st Floor, Plant T9, No.388, Jing'er Road, Tianjin Air Port Industrial Park, 300308 Tianjin, China**
EU Authorized Representative:	**Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany**
SRN	**DE-AR-000000001**
Dimdi No.	**DE/0000040627**

We declare under our sole responsibility that:

Name of the medical device:	**Safety Lancet**
SRN:	**CN-MF-000015849**
Registration No.:	**HZ 2027260-1**
Catalogue number:	**None**
Product code:	**EMDN code:V010401 - Lancets With Safety Systems, Single-Use**
Product model:	**XIII, XVII, XXI, XXII, XXIII, XXIV, XXV, XXVI, XXVIII, XXIX, XXX, XXXI, XXXII, XXXIII, XXXV, XXXIV, XXXVI**
Product specification:	**16G, 17G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G, 31G, 32G, 33G, 34G, 35G, 36G, 37G, 38G**
Intended purpose：	**The safety lancets are single use medical devices, which are designed to collect capillary blood sample.**
Basic UDI-DI:	**Model: XIII, XVII, XXI, XXII, XXIII, XXIV, XXV, XXVIII, XXX, XXXIV, XXXVI (69571386SL02WU)** **Model: XXVI, XXIX, XXXIII, XXXV (69571386SL06X4)** **Model: XXXI, XXXII (69571386SL17X9)**
Trade name:	**None**
of class:	**Rule6, Class IIa** according to annex VIII of Regulation (EU) 2017/745
Conformity assessment:	**REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I and III**
Notified Body:	**TÜV Rheinland LGA Products GmbH**
NB Identification number:	**CE 0197**
CS reference:	**None**

The declaration of conformity is issued under the sole responsibility of the manufacturer, and the device that is covered by the present declaration is in conformity with the Regulation EU 2017/745(MDR).

Place, Date of Issue: Tianjin, China, 2025.10.30

Signature: Ying Yuan

Name of Authorized Signatory: Ying Yuan

Function in Company: PRRC