 华鸿	Tianjin Huahong Technology Co., Ltd.	No.	HH-JS-TF-001-05
		Revision:	A/1
		Effective:	2023-04-21
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EU Declaration of conformity


Of

Twist-off lancet (use with lancing device)

File number: HH-JS-TF-001-05

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EU DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Tianjin Huahong Technology Co., Ltd.
A01, Plant B, No.278, Hangkong Road, Tianjin Pilot Free Trade Zone (Air Port Industrial Park), Tianjin 300308, 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: **Twist-off lancet (use with lancing device)**

SRN: **CN-MF-000015849**

Registration No.: **HZ 2027260-1**

Catalogue number: **None**

Product code: **EMDN code:V010402 - Lancets Without Safety Systems, Single-Use**

Product model: **I (IA, IB, IC, ID, IE, IK, IL, IM),II (IIA, IIB),III,V,VI**

Product specification: **16G, 18G, 19G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G, 28G, 29G, 30G, 31G, 32G, 33G, 34G, 36G, 38G**

Intended purpose: **The Twist-off lancet (use with lancing device) is a single use, sterile medical device, which is designed for use of micro blood sampling puncture to obtain capillary blood samples from the fingertip. The twist-off lancet needs using with lancing device.**

Basic UDI-DI: **69571386TOL01YF**

Trade name: **None**

of class: **Rule6, Class IIa**
according to annex VIII of Regulation (EU) 2017/745

Conformity assessment: **Annex IX of Regulation (EU) 2017/745**

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: **Tianjing, China, 2023.04.21**

Signature: 

Name of Authorized Signatory: **Meicheng Dong**

Function in Company: **PRRC**