

	Tianjin Huahong Technology Co., Ltd.	No.	HH-JS-TF-001-05
		Revision:	A/1
		Effective:	2023-04-21
Technical File of Twist-off lancet (use with lancing device)		Page:	Page 1 of 3

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