

EU Certificate

Quality Management System

REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.: HZ 2027260-1

Manufacturer: **Tianjin Huahong Technology Co., Ltd.**
A01, Plant B, No. 278, Hangkong Road, Tianjin Pilot Free Trade Zone (Air Port
Industrial Park), 300308 Tianjin, P.R. China

EUDAMED Single
Registration No.: CN-MF-000015849

Products: Products for IIa:
V010402 - LANCETS WITHOUT SAFETY SYSTEMS, SINGLE-USE
V010401 - LANCETS WITH SAFETY SYSTEMS, SINGLE-USE
A010101 - HYPODERMIC NEEDLES

Authorised
representative(s): Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, Germany

Certificate history

Revision:	Description:	Issue date:
0	Initial Revision	2023-04-13

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

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TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.