EU Certificate

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

TÜVRheinland®

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

Digitally signed by Şarco Alexandru
Date: 2024.03.20 08:52:01 EET
Reason: MoldSign Signature
Location: Moldova

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.

Report No.: 244410445-200

Effective date: 2023-04-13

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Issue date: 2023-04-13

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

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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.