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 2514782-1
Manufacturer:	SHENZHEN HAINWISE MEDICAL TECHNOLOGY CO., LTD. c701, Building B4, Yingzhan Science and Technology Park, No.22 longwo 4th Road, Longtian Street, Pingshan District, Shenzhen, 518122 Guangdong P.R. China
EUDAMED Single Registration No.:	CN-MF-000037066
Products:	Products of class IIa: C040201 - PERIPHERAL VASCULAR DIAGNOSTIC GUIDEWIRES U0601 - UROLOGICAL GUIDEWIRES, HYDROPHILIC U0602 - UROLOGICAL GUIDEWIRES, NOT HYDROPHILIC U0699 - UROLOGICAL GUIDEWIRES - OTHER
Authorized representative(s):	Kingsmead Service B.V. Zonnehof 36, 2632 BE, Nootdorp, Netherlands

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2025-04-21

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.:	10924150-120
Effective date:	2025-04-21
Expiry date:	2030-04-20
Issue date:	2025-04-21

Samuel Qin
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

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

Digitally signed by Jighili Tatiana
Date: 2025.12.15 13:49:24 EET
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