EU Quality Management System Certificate CN25/00004868

The management system of

Guangzhou Phoenix Medical Equipment Co., LTD.

Room 601 and 602, Building A, No.296, Ruixiang Road, Huangpu District, Guangzhou, 510760, Guangdong, P.R. China

SRN Number: CN-MF-000012210

has been assessed and certified as meeting the requirements of

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

For the following products

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 17 July 2025 until 17 July 2030 and remains valid subject to satisfactory surveillance audits.
Recertification audit due before 17 January 2030

Issue 1. Certified since 17 July 2025

Authorised by
Virginie Siloret
Global Medical Device
Certification Manager

SGS Belgium NV NB1639
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EU Quality Management System Certificate
CN25/00004868, continued

Guangzhou Phoenix Medical Equipment Co., LTD.

MDR (EU) 2017/745 Quality Management System certificate (Annex IX Chapter I and III)

Class IIb device
MDA0306 MDS1004 MDS1009 MDS1010 EMDN: Z120902

Haemodialysis Machine used for the blood purification therapy for chronic kidney failure patients Model: DORA-6000 (Basic UDI-DI: 697432511087 84Y2)

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Limitation: N/A

Certification is based on following reports: - CN/CAN/261962 - S2A 1.3 + TFR 1.1
Authorized representative name and address (if relevant): MedNet EC-REP C IIb GmbH, Borkstrasse 10, 48163 Münster, Germany
Previous certificate number: N/A
Change in between this certificate and previous one: N/A