

EU Quality Management System Certificate CN24/00006331

The management system of

# Beijing Konted Medical Technology Co., Ltd

Room 111, 1F, Building 3, No. 27, Yongwang Road, Daxing Biological Pharmaceutical Industry Base, Daxing District, Beijing, P.R. China  
SRN Number: CN-MF-000024104

has been assessed and certified as meeting the requirements of  
**MDR EU Quality Management System certificate (Annex IX QMS)**

For the following products  
**The Scope of Registration appears on page 2 of this certificate**

This certificate is valid from 09 October 2024 until 09 October 2029 and remains valid subject to satisfactory surveillance audits.

Recertification audit due date 09 April 2029

Issue 1. Certified since 09 October 2024



Authorised by

Virginie Siloret

Global Medical Device  
Certification Manager

SGS Belgium NV NB1639

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EU Quality Management System Certificate CN24/00006331,  
continued

**SGS**

# Beijing Konted Medical Technology Co., Ltd

## MDR EU Quality Management System certificate (Annex IX QMS)

Issue 1

Class IIa device - MDA0202, MDS1009

Pocket Ultrasound System for diagnostic ultrasound imaging and fluid flow analysis  
(Model: C10).

Basic UDI-DI: 697387564C10SU

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/BSJ/258232 - S2A 1.3

Authorized representative name and address (if relevant): SUNGO Cert GmbH ; Harffstr. 47,40591

Dusseldorf, Germany

Previous certificate number: N/A

Change in between this certificate and previous one: N/A

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