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EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR [redacted]

Manufacturer: Changzhou Centrau Medical Instrument Co.,Ltd.

Address:
(Building 5) No.5, Hexiang Road
Jiangsu Wujin Economic Development Zone
Changzhou
213000
China

Single Registration Number: CN-MF-000027491

EU Authorised Representative: Phoenix Medtech GmbH

Address:
Koenigsberger Strasse 11
64839 Muenster Hessen
Germany

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2025-07-18**

Current Issue Date: **2025-07-18**

Starting Validity Date: **2025-07-18**

Expiry Date: **2030-07-17**

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Regulation (EU) 2017/745, Annex XI Part A

MDR [redacted]

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Measure Ruler	Class Im, Class Ir
Retractor	Class Ir
Osteotome	Class Ir
Forceps	Class Ir
Guide Sleeve	Class Ir
Guide Device	Class Ir
Bender	Class Ir
Cutter	Class Ir
Screwdriver	Class Ir
Handle	Class Ir
Template	Class Ir
Hook	Class Ir
Awl	Class Ir
Nails Guide Device Component Part	Class Ir
Sliding Hammer Component Part	Class Ir
Protector	Class Ir
Reductor	Class Ir
Trial	Class Ir
Reamer	Class Ir
Tap	Class Ir
Guide Wire	Class Ir
Flexible Reamer	Class Ir
Rasp	Class Ir
Curette	Class Ir

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Regulation (EU) 2017/745, Annex XI Part A

MDR [redacted]

Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Trauma Instrument Set Series	Class Im, Class Ir
Cervical and Spine Instrument Set Series	Class Im, Class Ir
Joints Instrument Set Series	Class Im, Class Ir
Sports Medicine Instrument Set Series	Class Im, Class Ir
Dental Instrument Set Series	Class Ir

For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.

For Class Ir devices (Class I re-usable surgical instruments), the Notified Body conformity assessment is limited to the aspects relating to the reuse of the device.

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MDR [redacted]

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	[redacted]	Issued

First Issue Date: **2025-07-18**

Current Issue Date: **2025-07-18**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.