

EU Quality Management System Certificate CN25/00002864

The management system of

# WUHAN MINDRAY SCIENTIFIC CO., LTD.

Building 5, No.18, Jiulong South Road, East Lake High-Tech Development Zone, Wuhan,  
Hubei, 430206, P. R. China  
SRN Number: CN-MF-000032692

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 30 March 2026 until 30 April 2030 and remains valid subject to satisfactory surveillance audits.

Recertification audit due before 31 October 2029

Issue 6. Certified since 30 April 2025



Authorised by  
Virginie Siloret

Head of Certification and  
Compliance

SGS Belgium NV NB1639

SGS House Noorderlaan 87 2030 Antwerp Belgium

t +32 (0)3 545-48-48 - [www.sgs.com](http://www.sgs.com)

This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.



# WUHAN MINDRAY SCIENTIFIC CO., LTD.

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

Class IIa devices:

MDN1207

Reusable Resectoscope Outer Sheaths, Resectoscope Inner Sheaths, Obturators, Working Elements  
[Basic UDI-DI: 697728811A065000269N]

Non-Sterile Rigid Endoscope

(Model: M 00430A/G 00430A/M 00412A/G 00412A/M 02930A/G 02930A/M 02912A/G 02912A/M  
00430PA/G 00430PA/M 00412PA/G 00412PA/M 02930PA/G 02930PA/M 02912PA/G 02912PA)

[Basic UDI-DI: 697728811A065000259L]

Non-Sterile Rigid Endoscope

(Model: M 02900A, M 02930A, G 02900A, G 02930A, M 02900PA, M 02930PA, G 02900PA, G 02930PA,  
M 00400A, M 00430A, M 00470A, G 00400A, G 00430A, G 00470A, M 00400PA, M 00430PA, M  
00470PA, G 00400PA, G 00430PA, G 00470PA)

[Basic UDI-DI: 697728811A065000229E]

Reusable Cysto-Urethroscope Sheaths, Obturators, Inserts with Albarran Deflector, Endoscope Bridges

[Basic UDI-DI: 697728811A065000239G]

MDA0204, MDS1005

Sterile Single-Use Cysto-Nephroscope

[Basic UDI-DI: 697728811A065000219C]

Sterile Single-Use Ureteroscope

[Basic UDI-DI: 697728811A0650001097]

Class IIb devices:

MDA0312, MDS1009, EMDN code: K020199

Electrosurgical Platform intended for use with monopolar and bipolar accessories for cutting and  
coagulating tissue

(Model: EP300, EP300B, EP300C, EP300D)

[Basic UDI-DI: 697728811A0510000273]

MDA0312, EMDN code: Z120207

Reusable Plasma Electrode intended for endoscopic diagnosis and treatment in urological and  
gynecological applications

(Model: X E10260BM / X E102609M / X E102605M / X E10220CM / X E112209M / X E102609L / X  
E102605L / X E10260BL / X E102605N / X E102205N / X E10260BR / X E102609R / X E102609V)

[Basic UDI-DI: 697728811A065000289S]

This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.



EU Quality Management System Certificate  
CN25/00002864, continued

# WUHAN MINDRAY SCIENTIFIC CO., LTD.

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

MDA0312, MDS1005, EMDN code: Z120207

Sterile Disposable Plasma Electrode intended for endoscopic diagnosis and treatment in urological and gynecological applications

(Model: X E302605L / X E302609L / X E30260BL / X E302605M / X E302609M / X E30260BM / X E302609R / X E30260BR / X E302609V / X E302605N / X O302609L / X O302609M / X O302609R / X O302605N)

[Basic UDI-DI: 697728811A065000249J]

MDA0312, MDS1005, EMDN code: K020201

Sterile Ultrasonic Surgical Instrument are indicated for soft tissue incisions and sealing vessels in open and endoscopic surgery.

(Model: FC-14, FC-23, FC-36, FC-45, FCH-14, FCH-23, FCH-36, FCH-45, FOK-14, FOK-23, FOK-36, FOK-45, FOM-14, FOM-23, FOM-36, FOM-45, PC-14, PC-23, PC-36, PC-45, PCH-14, PCH-23, PCH-36, PCH-45, POK-14, POK-23, POK-36, POK-45, POM-14, POM-23, POM-36, POM-45, POS-14, POS-23, POS-36, POS-45, PCT-14, PCT-23, PCT-36, PCT-45, FOS-14, FOS-23, FOS-36, FOS-45, FCT-14, FCT-23, FCT-36, FCT-45, FO-14, FO-23, FO-36, FO-45)

[Basic UDI-DI: 697728811A0510000375]

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/SZX/312715 - ESG 1.5

Authorized representative name and address (if relevant): Shanghai International Holding Corp. GmbH (Europe) ; : Eiffestraße, 80 20537 Hamburg Germany

Previous certificate number: N/A

This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions | SGS](#). Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.



EU Quality Management System Certificate  
CN25/00002864, continued

# WUHAN MINDRAY SCIENTIFIC CO., LTD.

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

Change in between this certificate and previous one:

- 1.Change of SRN number, company name description and address description
- 2.Addition of new site
- 2.Remove MDS1005 code of Reusable Plasma Electrode from the scope
- 3.Addition of new devices into the scope

This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.





EU Quality Management System Certificate  
CN25/00002864, continued

# WUHAN MINDRAY SCIENTIFIC CO., LTD.

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

Issue 6

### Sites

WUHAN MINDRAY SCIENTIFIC CO., LTD.

Building 5, No.18, Jiulong South Road, East Lake High-Tech Development Zone, Wuhan, Hubei, 430206, P. R. China

WUHAN MINDRAY SCIENTIFIC CO., LTD.

Zone A, No.828, Gaoxin Avenue, East Lake High-Tech Development Zone, Wuhan, Hubei, 430206, P. R. China

WUHAN MINDRAY SCIENTIFIC CO., LTD.

Zone A, No.18, Jiulong South Road, East Lake High-Tech Development Zone, Wuhan, Hubei, 430206, P. R. China

This document is an authentic electronic certificate for Client' business purposes use only. Printed version of the electronic certificate are permitted and will be considered as a copy. This document is issued by the Company subject to SGS General Conditions of certification services available on [Terms and Conditions](#) | SGS. Attention is drawn to the limitation of liability, indemnification and jurisdictional clauses contained therein. This document is copyright protected and any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful.

