EC CERTIFICATION

EU Quality Management System Certificate
EU Regulation 2017/745 for Medical Devices, Annex IX Chapters I & III

We hereby declare that a conformity assessment based on a quality management system and technical documentation restricted to the aspects relating to the conformity of the devices with reusability requirements - has been carried out following the requirements of Regulation (EU) 2017/745 for Medical Devices.

We certify that the documentation conforms to the relevant provisions of the aforementioned regulation, and the result entitles the organization to use the CE 2862 marking on the products listed below.

Certificate Number:
28620170857

Revision:
01

Initial Certification Date:
26 March 2024

Date of Certification Decision:
5 December 2024

Certificate Issue Date:
5 December 2024

Certificate Expiry Date:
29 March 2028

MPS Micro Precision Systems AG

Chemin du Long-Champ 95,Biel-Bienne, 2504, Switzerland

Manufacturer SRN: CH-MF-000032439

Authorised Representative Name
Emergo Europe B.V
Westervoortsedijk 60, 6827 AT, Arnhem, The Netherlands

Scope:

- Reusability aspects of devices as detailed in attached product list.

Brian Mather
Certification Authority, MDR
Intertek Medical Notified Body AB,
Torshamnsgatan 43,
Box 1103, SE-164 22 Kista, Sweden

Intertek Medical Notified Body AB is a Notified Body in accordance with the requirements set out in EU Regulation 2017/745 on medical devices, with the identification number 2862.

In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organisation maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. The certificate remains the property of Intertek, to whom it must be returned upon request

PRODUCT LIST FOR CERTIFICATE

See attached Product List

EXAMINATION AND TESTS PERFORMED

Last Audit report reference	**Stage 1 audit ACTY-2022-522312**
	Stage 2 audit ACTY-2022-522313
	CN00143-07
	CN00143-13

CONDITIONS FOR OR LIMITATIONS TO VALIDITY OF CERTIFICATE

CERTIFICATE HISTORY

PRECEDING CERTIFICATE NUMBER	DATE OF ISSUE	IDENTIFICATION OF CHANGES
28620170857	26 Mar 2024	Initial Issue
28620170857-01	5 Dec 2024	Corrections to certificate

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PRODUCT LIST FOR CERTIFICATE

Issued to: MPS Micro Precision Systems AG

Certificate number: 28620170857-01

Certificate valid from: 2024-12-05

Product list issue date:
05 October 2026

Product	Classification and EMDN	Intended use[1]	Date Added
Class I reusable surgical instruments			
Basic UDI-DI: 764018791GUIDEWIRE01DC			
T1150 - Straight guide Ø3 x 820 mm	Class I(r) L0922		2024-03-26
T1152 - Straight guide Ø3 x 440 mm	Class I(r) L0922		2024-03-26
T12422 - Straight guide Ø3 x 820 mm	Class I(r) L0922		2024-03-26
T15416 - Straight guide Ø3 x 510 mm	Class I(r) L0922		2024-03-26
T16469 - Straight guide Ø3 x 600 mm	Class I(r) L0922		2024-03-26
T18905 - QuickSwitch Guide Wire Ø3 x 1000 mm	Class I(r) L0922		2026-10-05
T18924 - QuickSwitch Guide Wire Ø3 x 1000 mm	Class I(r) L0922		2026-10-05
T602 - Straight guide Ø2 x 820 mm	Class I(r) L0922		2024-03-26

Lian Zhang

Lian Zhang
Certification Authority, MDR
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[1]The intended use is only included for class IIb devices and devices covered by an EU technical documentation certificate.