EC CERTIFICATE

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

No. 5-921-200-2105

The **NEOEMKI National Medical Device Conformity Assessment and Certification LLC.** certifies that the manufacturer:

EMD Endoszkóp Műszer Gyártó és Kereskedelmi Kft.
Bartók Béla u. 113/B
4031 Debrecen
Hungary

for the products / product categories:

Surgical and endoscopic instruments and devices

applies a quality system which meets the requirements of Directive 93/42/EEC concerning medical devices, Annex II.

Registry number of the related audit report is **NE/1097/2021**. The assessment was based on a remote audit.

This certificate is valid until **2024-05-26** supposed that the remote audit is followed by a successful on-site audit in 6-12 months and the results of the regular yearly surveillance audits are satisfactory.

Issued by NEOEMKI LLC as a Notified Body with identification number **1011**.

This certificate is valid only with the attachment.

Budapest, 2021-05-10

EMKI 2725

The authenticity and validity of the certificate are verifiable at NEOEMKI LLC.

ATTACHMENT TO EC CERTIFICATE

Additional information for Certificate No. 5-921-200-2105

The certificate is valid for the following products / models:

Surgical and endoscopic instruments and devices	*CLASS*
Trocar systems	IIa
Laparoscopic instruments	IIb
Sterile cranial perforators for single use	IIa
Reusable cranial perforators	IIa
Sterile high speed tools for high speed motor systems	IIa
High speed motor systems	IIb

Issue: 1 Date: 2021-05-10 First issued: 2021-05-10

EMKI

EMD Endoszkóp Műszer Gyártó és Kereskedelmi Kft
Bartók Béla u. 113/B,
Debrecen 4031 Hungary

Date: 22 May 2024

Confirmation Letter
Reference: HU_003387_2024_02

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, HTCert, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 2803 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR from the following manufacturer:

EMD Endoszkóp Műszer Gyártó és Kereskedelmi Kft
Bartók Béla u. 113/B, Debrecen 4031 Hungary
SRN: HU-MF-000003387

Application ID: HU_003387_24_4_01
Application Date: 16/05/2024

The devices covered by the formal application mentioned above are identified below. HTCert has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)

- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

Certification Director

Devices covered by this letter

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
NeuroSmart High-speed Motor System and accessories	Class IIb	n/a	5-921-200-2105 NB 1011
NeuroLine Disposable Cranial Perforator	Class IIa	n/a	5-921-200-2105 NB 1011
NeuroLine Reusable Cranial Perforator	Class IIa	n/a	5-921-200-2105 NB 1011
EndoLine Trocar System	Class IIa	n/a	5-921-200-2105 NB 1011
EndoLine Laparoscopic instruments	Class IIb	n/a	5-921-200-2105 NB 1011

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/21	HU_003387_2024_01	Initial issue
2024/05/22	HU_003387_2024_02	Wording correction on device name