

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.

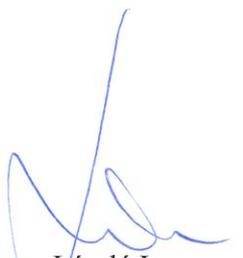
Registry number of the related audit report is **NE/1097/2021**. The assessment was based on a remote audit.

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


László Imre
Managing Director



EMKI 2725

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

neoEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.
neoEMKI National Medical Device Conformity Assessment and Certification LLC.

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neoEMKI

ATTACHMENT TO EC CERTIFICATE

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

The certificate is valid for the following products / models:

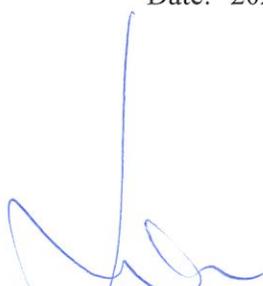
Surgical and endoscopic instruments and devices

	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


László Imre
Managing Director



EMKI