Number: *NLO-xxxxxxxxxx*

DECLARATION OF CONFORMITY

Manufacturer: *EMD Endoszkóp Műszer Gyártó és Kereskedelmi Kft.*
H-4031 Debrecen, Bartók Béla u. 113/B

Product: *NeuroLine Disposable Cranial Perforator with Hudson End*

Type: *NLO-6/9-1.5, NLO-6/9-3.0, NLO-7/11-1.5, NLO-7/11-3.0, NLO-9/13-1.5, NLO-9/13-3.0, NLO-11/14-1.5, NLO-11/14-3.0*

Class: *II.a*

Here by we certify that the product(s) described above meet the requirement of the following directives and relating harmonized standards :

Document no.	***Title***
MDD 93/42/EEC Annex II. without Article 4.	*Directive for Medical Devices*
4/2009. (III. 17.)	*Order of Ministry of Health applies for the medical devices*
EN ISO 13485:2016	*Medical devices. Quality management systems. Requirements for regulatory purposes*
EN 1041:2008	*Information supplied by the manufacturer of medical devices*
EN ISO 15223-1:2016	*Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements*
EN 62366:2008	*Medical devices. Application of usability engineering to medical devices*
EN ISO 10993-1:2009/AC:2010	*Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process*
EN ISO 10993-5:2009	*Biological evaluation of medical devices. Part 5: Tests for in vitro cytotoxicity*
EN ISO 10993-10:2013	*Biological evaluation of medical devices. Part 10: Tests for irritation and skin sensitization*
EN ISO 14971:2012	*Medical devices. Application of risk management to medical devices*
EN 556-1:2001/AC:2006	*Sterilization of medical devices. Requirements for medical devices to be designated „STERILE". Part 1: Requirements for terminally sterilized medical devices*
EN ISO 11137-1:2015/AC:2019	*Sterilization of health care products. Radiation. Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*
EN ISO 11137-2:2015	*Sterilization of health care products. Radiation. Part 2: Establishing the sterilization dose*
EN ISO 11607-1:2009	*Packaging for terminally sterilized medical devices. Part 1: Requirements for materials, sterile barrier systems and packaging systems*
EN ISO 11607-2:2006	*Packaging for terminally sterilized medical devices. Part 2: Validation requirements for forming, sealing and assembly processes*
EN ISO 11737-1:2006/AC:2009	*Sterilization of health care products. Microbiological methods. Part 1: Determination of a population of microorganisms on products*

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DECLARATION OF CONFORMITY

EN ISO 11737-2:2009	*Sterilization of medical devices. Microbiological methods. Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*	
Notified Body code/name:		
1011	NEOEMKI Nemzeti Orvostechnikai Eszköz Megfelelőségértékelő és Tanúsító Kft.	*H-1097 Budapest, Albert Flórián út 3/a.*
EC Certificate number/expiry date:		
5-921-200-2105	*CE Approval, Directive 93/42/EEC Annex II. without Article 4., Full Quality Assurance System, Medical Devices*	***Expiry date*** *26.05.2024*
4-556-135-2111	*Quality Management System Certificate, ISO 13485*	***Expiry date*** *11.11.2024*

24.01.2023.

Debrecen, Hungary

EMD Kft.
4031 Debrecen, Bartók Béla u. 11
adószám: 11557379-2-09
3.

Ujváriné Németh Anikó

Ujváriné Németh Anikó
MIR vezető/ Quality manager