

# EC CERTIFICATE

## Full Quality Assurance System

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

No. 5-881-200-2004

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

**SUMI spółka z ograniczoną odpowiedzialnością sp. k.**  
**ul. Drobiarska 35**  
**05-070 Sulejówek**  
**Poland**

for the products / product category:

**Sterile and non sterile plastic medical 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: **NE/1039/2020**

This certificate is valid until **2024-05-26** supposed that 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.

Issue: 2

First issued by the Directorate of Device Testing and Clinical Engineering (EMKI) on 27 April 2020.

Budapest, 2021-02-22

  
László Imre  
Managing Director



EMKI 2666

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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[www.emki.hu](http://www.emki.hu)



# ATTACHMENT TO EC CERTIFICATE

Page 1 of 1

## Additional information for certificate number 5-881-200-2004

This certificate is valid for the following Class IIa & IIb products:

Tracheal tubes, class IIa  
Tracheal tubes accessories, class IIa  
Tracheal intubation stylets, introducers, guides, class IIa  
Bronchial tubes, single and double lumen, class IIa  
Bronchial tubes accessories and connectors, class IIa  
Tracheostomy double lumen bronchial tubes, class IIa  
Laryngeal masks, class IIa  
HiCapno, class IIa  
Suction catheters, class IIa  
Stomach tubes, class IIa  
Duodenal tubes, class IIa  
Suction handles, class IIa  
Suction handles, set, class IIa  
Suction handles, with filter, class IIa  
Closed suction systems, class IIa  
Silicone corrugated breathing tubings, class IIa  
Cricothyrotomy set, class IIa  
Tubing set for graft extraction hand piece, class IIa  
Tubing set for implanting hand piece, class IIa  
Percutaneous tracheostomy set, class IIa  
Tracheostomy tubes, class IIb  
KAN tracheostomy tubes, class IIb  
SUMINI tracheostomy tubes, class IIb  
Tracheostomy tubes accessories, class IIb  
Feeding tubes, class IIb  
Urology catheters - Nelaton, Tiemann, Couvelaire, class IIb

This certificate is valid for the following Class I sterile products \*:

Guedel airways  
Nasal oxygen set  
Nasopharyngeal airways

Suction connecting tubes  
Connectors, adaptors  
Tubings, bubble tubings, silicone tubings

\* The assessment of the quality system is restricted to the aspects of manufacture concerned with securing and maintaining sterile condition of the product.

Issue: 2

Date: 2021-02-22

First issued: 2020-04-27

  
László Imre  
Managing Director



EMKI

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