

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 Sulejówiek
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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ATTACHMENT TO EC CERTIFICATE

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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



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