

EC CERTIFICATE

Full Quality Assurance System

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

No. 5-831-200-1801

The Directorate of Device Testing and Clinical Engineering (EMKI)

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: **42-145-2007**

This certificate is valid until **2023-01-15** supposed that the results of the regular yearly surveillance audits are satisfactory.

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

This certificate is valid only with the attachment.

Issue: 4

First issued: 2018-01-16

Budapest, 2020-02-04



Head of EMKI



EMKI 2340

The authenticity and validity of the certificate are verifiable at EMKI.

ATTACHMENT TO EC CERTIFICATE

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Additional information for Certificate No. 5-831-200-1801

The certificate is valid for the following products:

<i>Sterile and non sterile plastic medical devices</i>		Classification
Part I	Tracheal tubes	IIa
	Tracheal tubes accessories	IIa
	Double lumen bronchial tubes	IIa
	Single lumen bronchial tubes	IIa
	Tracheostomy double lumen bronchial tubes	IIa
	Bronchial tubes accessories	IIa
	Bronchial tubes connectors	IIa
	Stylets, intruducers, guides	IIa
	Guedel airways	I sterile
	Laryngeal masks	IIa
	Nasopharyngeal airways	I sterile
	Silicone tubes	IIa
Part II	Tracheostomy tubes	IIb
	Tracheostomy tubes KAN	IIb
	Tracheostomy tubes SUMINI	IIb
	Tracheostomy tubes accessories	IIb
	Cricothyrotomy set	IIa
Part III	Nasal oxygen set	I sterile
	H-CapnO2Mask	IIa
Part IV	Stomach tubes	IIa
	Duodenal tubes	IIa
	Feeding tubes	IIb
	Control valve suction catheters	IIa
	Suction catheters	IIa
	Urology catheters Nelaton, Tiemann, Couvelaire	IIb
	Closed suction system	IIa
Part V	Connectors, adaptors	I sterile
	Suction connecting tubes	I sterile
	Connecting tubes	I sterile
	Tubings	I sterile
	Bubble tubings	I sterile
	Suction handles-set	IIa
	Suction handles	IIa
	Suction handles with filter	IIa
	Tubing set for graft extraction hand piece, Tubing set for implanting hand piece	IIa

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EMKI

Eszközminősítő és Kórháztechnikai Igazgatóság
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