

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.

Budapest, 2018-01-16



Head of EMKI



EMKI 1827

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

ATTACHMENT TO EC CERTIFICATE

Page 1 of 1

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

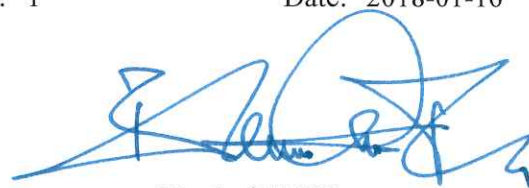
The certificate is valid for the following products:

<i>Sterile and non sterile plastic medical devices</i>		Classification
Part I	Tracheal tubes	Ia
	Tracheal tubes accesories	Ia
	Double lumen bronchial tubes	Ia
	Single lumen bronchial tubes	Ia
	Tracheostomy double lumen bronchial tubes	Ia
	Bronchial tubes accesories	Ia
	Bronchial tubes connectors	Ia
	Stylets, intruducers, guides	Ia
	Guedel airways	I sterile
	Laryngeal masks	Ia
	Nasopharyngeal airways	I sterile
	Silicone tubes	Ia
Part II	Tracheostomy tubes	Iib
	Tracheostomy tubes KAN	Iib
	Tracheostomy tubes accesories	Iib
Part III	Nasal oxygen set	I sterile
	H-CapnO2Mask	Ia
Part IV	Stomach tubes	Ia
	Duodenal tubes	Ia
	Feeding tubes	Iib
	Control valve suction catheters	Ia
	Suction catheters	Ia
	Urology catheters Nelaton, Tiemann, Couvelaire	Iib
	Closed suction system	Ia
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	Ia
	Suction handles	Ia
	Suction handles with filter	Ia

Issue: 1

Date: 2018-01-16

First issued: 2018-01-16



Head of EMKI



EMKI

Eszközminősítő és Kórháztechnikai Igazgatóság
Directorate of Device Testing and Clinical Engineering

H-1097 Budapest, Albert Flórián út 3/A, Telefon: +36 20 268 75 95, Fax: +36 1 886 93 33

E-mail: cert@emki.hu, Web: www.emki.hu

H-1051 Budapest, Zrínyi u. 3. (1372 P.O. Box 450.)

