Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

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

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date May 13, 2024

Notified Body Confirmation Letter
Reference. : SUMI_PLAQ1_2024_04_25 / 84973926

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

SUMI spółka z ograniczoną odpowiedzialnością sp.k.
ul. Drobiarska 35
05-070 Sulejówek
Poland
PL-MF-000010592

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Digitally signed
by Daniel Świątko
Date: 2024.05.13
10:51:00 +02'00'

Daniel Swiatko
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
TRACHEAL TUBES	IIa	Tracheal tubes	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
TRACHEAL TUBES	IIa	Tracheal tubes	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
BRONCHIAL TUBES	IIa	Bronchial tubes single and double lumen	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
BRONCHIAL TUBES	IIa	Bronchial tubes single and double lumen	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
TRACHEOSTOMY DOUBLE LUMEN BRONCHIAL TUBES	IIa	Bronchial tubes single and double lumen	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
TRACHEOSTOMY DOUBLE LUMEN BRONCHIAL TUBES	IIa	Bronchial tubes single and double lumen	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
BRONCHIAL TUBES ACCESSORIES	IIa	Bronchial tubes accesories and connectors	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
LARYNGEAL MASKS	IIa	Laryngeal mask	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
GUEDEL AIRWAYS	Is	Guedel airways	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
NASOPHARYNGEAL AIRWAYS	Is	Nasopharyngeal airways	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
TRACHEOSTOMY TUBES ACCESSORIES	IIa	Tracheostomy tubes accessories	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
CATHETER MOUNTS	IIa	Tracheal tubes accessories	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
CRICOTHYROTOMY SET	IIa	Cricothyrotomy set	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
PERCUTANEOUS TRACHEOSTOMY SET	IIa	Percutaneous tracheostomy set	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
NASAL OXYGEN SET	IIa	Nasal oxygen set	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
STOMACH TUBES DUODENAL TUBES	IIa	Stomach tubes, Duodenal tubes	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
FEEDING TUBES	IIa	Feeding tubes	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
SUCTION CATHETERS	IIa	Suction catheters	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
CLOSED SUCTION SYSTEMS	IIa	Closed suction system	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
SUCTION CONNECTING TUBE, CONNECTOR, ADAPTOR, TUBBING, BUBBLE TUBING, SILICONE TUBING	Is	Suction connecting tubes, Connectors, Adaptors, Tubbings, Bubble tubings, silicone tubings	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
SUCTION HANDLES SUCTION HANDLES SET SUCTION HANDLES WIITH FILTER	IIa	Suction handles, Suction handles set, Suction handles wiith filter	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
STYLETS	Is	Tracheal intubation stylets, introducers, guides	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
INTRODUCERS, GUIDES	Is	Tracheal intubation stylets, introducers, guides	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
INTRODUCERS FOR INFANTS	Is	Tracheal intubation stylets, introducers, guides	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
GUIDES WITH VENTILATION LUMEN	IIa	Tracheal intubation stylets, introducers, guides	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
~~TRACHEOSTOMY TUBES ACCESSORIES~~	~~IIb non-implantable~~		
~~TRACHEOSTOMY TUBES ACCESSORIES~~	~~IIb non-implantable~~		
~~TRACHEOSTOMY TUBES ACCESSORIES~~	~~IIb non-implantable~~		
HICAPNO	IIa	HiCapno	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
SILICONE CORRUGATED BREATHING TUBES	IIa	Silicone corrugated breathing tubings	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
TUBING SET FOR GRAFT EXTRACTION HAND PIECE	IIa	Tubing set for graft extraction hand piece	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
TUBING SET FOR IMPLANTING HAND PIECE	IIa	Tubing set for implanting hand piece	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
UROLOGY CATHETERS	IIb non-implantable	Urology catheters Nelaton Tiemann Couvelaire	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
UROLOGY CATHETERS	IIb non-implantable	Urology catheters Nelaton Tiemann Couvelaire	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011
UROLOGY CATHETERS	IIb non-implantable	Urology catheters Nelaton Tiemann Couvelaire	Certificate MDD No.5-881-200-2004 NEOEMKI CE 1011

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
None			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/13	SUMI_CL607_2024_05_13	Initial issue