EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HZ 1023926-1
Manufacturer:	SUMI spółka z ograniczoną odpowiedzialnością sp.k. ul. Drobiarska 35 05-070 Sulejówek Poland
EUDAMED Single Registration No.:	PL-MF-000010592
Products:	Products of class IIb: R010501 - TRACHEOSTOMY AND LARINGECTOMY CANNULAS, TRACHEOSTOMY AND LARINGECTOMY CANNULAS AND KITS, UNCUFFED R010502 - TRACHEOSTOMY AND LARINGECTOMY CANNULAS, TRACHEOSTOMY AND LARINGECTOMY CANNULAS AND KITS, CUFFED R010503 - TRACHEOSTOMY AND LARINGECTOMY CANNULAS, TRACHEOSTOMY INNER CANNULAS
Authorized representative(s):	Not applicable

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	84957157-60
Effective date:	2024-04-09
Expiry date:	2029-04-08
Issue date:	2024-04-09

Daniel Świątko
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

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Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-04-09

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