

# EU Certificate

## Quality Management System REGULATION (EU) 2017/745 on Medical Devices Annex IX Chapters I and III

Registration No.: HZ 1023926-1

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

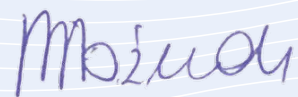
EUDAMED Single Registration No.: PL-MF-000010592

Products: Products of class IIa:  
R010301 - ENDOTRACHEAL TUBES, CUFFLESS  
R010302 ENDOTRACHEAL TUBES, CUFFED  
R010401 - ENDOBRONCHIAL TUBES, RIGHT  
R010402 - ENDOBRONCHIAL TUBES, LEFT  
R010480 - ENDOBRONCHIAL TUBES – ACCESSORIES  
R010502 - TRACHEOSTOMY AND LARINGECTOMY CANNULAS AND KITS, CUFFED

The Notified Body hereby declares that the requirements of Annex IX, Chapter I 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.: 84977787-30  
Effective date: 2025-10-07  
Expiry date: 2029-04-08  
Issue date: 2025-10-07



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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.



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### 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

| Certificate history |                       |             |
|---------------------|-----------------------|-------------|
| Revision:           | Description:          | Issue date: |
| 0                   | Initial certification | 2024-04-09  |
| 1                   | Scope extension       | 2025-10-07  |

