

Certificate

Quality Management System EN ISO 13485:2016 + AC:2018 + A11:2021 ISO 13485:2016

Registration No.: SX 1023926-1
Certificate Holder: SUMI spółka z ograniczoną
odpowiedzialnością sp.k.
ul. Drobiarska 35
05-070 Sulejówek
Poland

Scope: Design and development, manufacture and distribution of
sterile (EO) and non-sterile plastic made medical devices used
for anesthesiology, laryngology, surgery and gastrology.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 84989617-20
Effective date: 2026-03-25
Expiry date: 2029-03-24
Issue date: 2026-03-25
Replaces certificate SX 1023926-1 issued 2023-03-31

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


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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	SUMI spółka z ograniczoną odpowiedzialnością sp.k. ul. Drobiarska 35 05-070 Sulejówek Poland	Design and development, manufacture and distribution of sterile (EO) and non-sterile plastic made medical devices used for anesthesiology, laryngology, surgery and gastrology.
/02	SUMI spółka z ograniczoną odpowiedzialnością sp.k. ul. Zapaśników 14 05-074 Nowy Konik Poland	Storage and distribution of sterile (EO) and non-sterile plastic made medical devices used for anesthesiology, laryngology, surgery and gastrology.

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