

EU Quality Management System Certificate FI23/00000013

The quality management system of

# Gründler GmbH

Jaspisstraße 23, 72250 Freudenstadt, Germany

SRN: DE-MF-000025923

has been assessed and certified as meeting the requirements of

## Regulation (EU) 2017/745

on Medical Devices, Annex IX (I, III and TDA in Section 4)

For the following

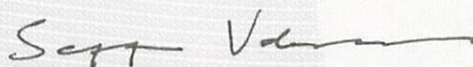
### Respiratory and Anaesthesia Devices

Devices covered, risk classification and applicable audit reports referred to, are listed in Attachment 1 of this certificate

This certificate is valid from 31 March 2023 until 30 March 2026  
and remains valid subject to satisfactory surveillance audits, and summaries of changes  
or scientific findings.

Issue 1. Certified since 31 March 2023

This certification is based on decision: FI23/08114P0



Seppo Vahasalo, NB Manager  
SGS Fimko Ltd., Notified Body 0598

**FINAS**  
Finnish Accreditation Service  
S009 (EN ISO/IEC 17021)



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Member of the SGS Group (SGS SA)

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# Attachment 1 to SGS Fimko Ltd. Quality Management System certificate FI23/00000013, issue 1

<b>Manufacturer</b>	Gründler GmbH.	<b>SRN DE-MF-000025923</b>
<b>Address</b>	Jaspisstraße 23, 72250 Freudenstadt, Germany	
<b>Other addresses covered by the certificate</b>	<b>Location</b>	<b>Activity at the location</b>
	N/A	N/A
<b>Activity and Device Category</b>	MDR (EU) 2017/745 Annex IX (I, III and TDA in section 4)	
<b>EU Authorised Representative</b>	N/A	

<b>Device or Device Group</b>	<b>Risk Class</b>	<b>Identification Details and Intended Purposes</b>
Respiratory and anaesthesia devices R9099 RESPIRATORY AND ANAESTHESIA DEVICES - OTHER	Ila	Product: Ventilation Base Device 150i Model: 000176 Intended purpose: Device for reduction of respiratory deadspace during invasive ventilation of patients
Respiratory and anaesthesia devices R9099 RESPIRATORY AND ANAESTHESIA DEVICES - OTHER	Ila	Product: Ventilation Patient Set Standard Model: 000070 Intended purpose: Accessory for Ventilation Base Device 150i

The certification decision is based on the following:

<b>Reports</b>	<b>Identification</b>	<b>Date</b>
Audit report	Gründler_V1-S2_FPMREG3019 - MDR Audit Report Ver D 2023-02-28	2023-02-28
Technical Documentation Assessment report	Gründler_V1_FPMREG3020 - MDR Technical Documentation Assessment Report Ver E 2023-03-29	2023-03-29

## Conditions for limitation to the validity of certificate

PMCF investigation is to be planned and conducted for the Ventilation Base Device 150i and Ventilation Patient Set Standard.

## Preceding certificate and its attachment 1

N/A