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

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

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

SGS Fimko Ltd
Takomotie 8, FI-00380 Helsinki, Finland
t. +358 9 696 361 www.sgs.fi
Business ID 0978538-5 Member of the SGS Group (SGS SA)

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

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

Device or Device Group	Risk Class	Identification Details and Intended Purposes
Respiratory and anaesthesia devices R9099 RESPIRATORY AND ANAESTHESIA DEVICES - OTHER	IIa	Product: Ventilution 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	IIa	Product: Ventilution Patient Set Standard Model: 000070 Intended purpose: Accessory for Ventilution Base Device 150i

The certification decision is based on the following:

Reports	Identification	Date
Audit report	Gründler_V1-S2_FPMDREG3019 - MDR Audit Report Ver D 2023-02-28	2023-02-28
Technical Documentation Assessment report	Gründler_V1_FPMDREG3020 - 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 Ventilution Base Device 150i and Ventilution Patient Set Standard.

Preceding certificate and its attachment 1
N/A