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 Annex IX (I and III)

for the following:
Respiratory and Anaesthesia Devices

Issue 2
Previous certificate's number and issue: FI23/00000013, Issue 1
Change in between this certificate and the previous one: Recertified, update of the certificate template

The devices covered, their risk classifications, codes applied, identification details, intended purposes, standards and common specifications followed, conditions or limitations, as well as applicable test and audit reports referred to, are listed on the subsequent pages of this certificate.

This certificate is valid from 31 March 2026 until 30 March 2029 and remains valid subject to satisfactory surveillance audits.
Certified since 31 March 2023
Certified activities performed by additional sites are listed on the subsequent pages.

Authorised by
Teuvo Vaara, Certifier

SGS FIMKO OY
Notified Body 0598 Takomotie 8, FI-00380 Helsinki, Finland
t +358 9 696 361 - www.sgs.fi - Business ID 0634247-4

Gründler GmbH

Regulation (EU) 2017/745 Annex IX (I and III)

Issue 2
Sites
Gründler GmbH Jaspisstraße 23, 72250 Freudenstadt, Germany Design, development, manufacturing, storage, distribution, sales, service, HR, QMS, management

Gründler GmbH

Regulation (EU) 2017/745 Annex IX (I and III)

Attachment 1 of Issue 2

Risk classes, codes, identification, and other relevant details of the certified devices:

Risk class IIa
MDA 0307, MDS 1009, MDT 2010, MDT 2011
R9099 Respiratory and anaesthesia devices - other
Ventilution Base Device 150i, Basic UDI-DI 426237137000951BQ, Model: 000176
Ventilution Patient Set Standard, Basic UDI-DI 426237137000952BS, Model: 000070

The certification decision is based on the following:

Report Identification and Date:
Audit report: FPMDREG3019 GRÜNDLER V1R-2025 Audit Report Ver G Rev_1, dated 2026-03-09
Gründler - V1R - FPMDREG3020 - MDR Technical Documentation Assessment Report Ver G 2026-03-05, dated, 2026-03-05

Applied Standards / Common specifications:
EN ISO 13485:2016 + A11/2021, EN ISO 14971:2019 + A11/2021, EN ISO 15223-1:2021, references to other relevant CS and harmonized standards are in the reports

Conditions for or limitation to the validity of the certificate:
PMCF investigation is to be planned and conducted for the Ventilution Base Device 150i and Ventilution Patient Set Standard.

EU Authorised Representative:
N/A