Gründler
medical

EU Declaration of Conformity

Manufacturer's Name:	Gründler GmbH
Manufacturer's Address:	Jaspisstraße 23, 72250 Freudenstadt, Germany
SRN (Single Registration Number):	DE-MF-000025923
Authorized Representative Name:	N/A
Authorized Representative Address:	N/A
Basic UDI-DI:	426237137000952BS
Name of the Device:	Ventilution Patient Set Standard
Production Period:	01.04.2023 – 30.03.2026
Product REF:	REF 000070
Purpose:	Reduction of deadspace
Classification:	IIa
Notified Body Name:	SGS Fimko Ltd
Notified Body Address:	Takomotie 8, FI-00380 Helsinki, Finland
Notified Body Identification Number:	0598
Related Certificate:	FI23/00000013
Conformity Assessment Route:	Gründler GmbH uses the following procedures for the CE-labeling of their products according to the Regulation MDR 2017/745: Class IIa: EU conformity declaration according to Annex IX.

This declaration of conformity is issued under the sole responsibility of Gründler GmbH. The above-mentioned product is a medical device according to article 2 (1) of the MDR 2017/745 and fulfils the basic safety and performance requirements according to Annex I. Conformity has been established by means of the above conformity assessment procedure, the corresponding provisions of the MDR 2017/745, the state of the art and the harmonized standards that have been applied. This declaration is supported by the Quality System approval to ISO 13485 issued by SGS Fimko Ltd. All supporting documentation is retained at the premises of the manufacturer. The declaration is valid with the date of the signature.

Signature:

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Dr. Christoph Gründler/CEO

Place and date of issue:

Freudenstadt, 2023-10-30

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Place and date

Gründler GmbH
Geschäftsführer:
Markus Gründler
Dr. med. Christoph Gründler
Amtsgericht Stuttgart
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