

Declaration of Conformity

DAMECA

Revision: B

Number: QSD4 -0018-F5

Tier: 4

Element: Technical File

Quality System Document

Manufacturer:

Dameca A/S

Islevdalvej 211,
DK-2610 Roedovre
Denmark
Phone: +45 44509990

Notified Body:

LNE/GMED, Rue Gaston Boissier; 75724 Paris Cedex 15, France
Identification number: 0459

EC Certificate no:

7789

Rev.: 11

We the Manufacturer declare under our sole responsibility that the product:

Product family:

Flow meter

Description:

Administer and regulate the flow of medical gases from a gas supply to the patient.

Product Number (P\N):

Product name	PN
O ₂ flow meter 1-15 L/min	32015-00
Air flow meter 1-16 L/min	32015C-00
Double O ₂ flow meter 1-15 L/min	32016-00
Double Air flow meter 1-16 L/min	32016C-00
Combined O ₂ and Air flow meter O ₂ 1-15 L/min Air 1-16 L/min	32031-00

GMDN code and Term:

42549 Anaesthesia gas flowmeter

Device Classification and Rule:

Ila, rule 2 of annex IX

Conformity Assessment Route:

Annex II (full quality assurance)

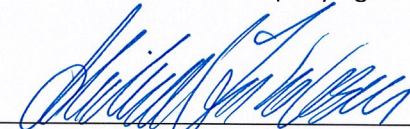
Technical file reference:

Technical File Index for Flow Meters

to which this declaration relates is in conformity with the provisions of the Council Directive: 93/42/EEC Medical Device Directive, as amended up to and inclusive 2007/47/EC.

The products listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation. Additionally, the products listed above have been designed, manufactured, tested, and found to be compatible with the devices and accessories described by the manufacturer in the devices accompanying documentation

Signature:



Michael Jakobsen
Quality & Regulatory Manager, Dameca A/S

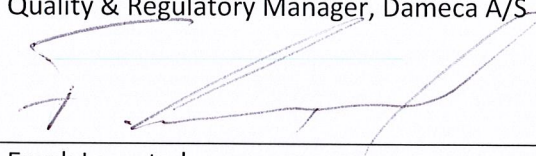
Date:

04 MARCH 2021

Place:

Roedovre, Denmark

Signature:



Frank Loevstad
CEO, Dameca A/S

Date:

5/3-2021

Place:

Roedovre, Denmark