

# Declaration of Conformity



## Manufacturer:

Dameca a/s,  
Islevdalvej 211,  
DK-2610 Roedovre, Denmark  
Phone: +45 44509990

**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 name	PN
O <sub>2</sub> flow meter 1-15 L/min.	32015-00
Air flow meter 1-16 L/min	32015C-00
Double O <sub>2</sub> flow meter 1-15 L/min	32016-00
Double Air flow meter 1-16 L/Min	32016C-00
Combined O <sub>2</sub> and Air flow meter O <sub>2</sub> 1-15 L/min Air 1-16 L/min	32031-00

GMDN code and Term: 42549 Anaesthesia gas flowmeter

Device Classification and Rule: IIa, rule 2 of annex IX

Conformity Assessment Route: Annex II (full quality assurance)


**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.

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

EC Certificate no: 7789


Signature: \_\_\_\_\_

  
Peter Jørgensen  
QA/RA Manager, Dameca a/s

Date of issue: 01 July 2016

Place of Issue: Roedovre, Denmark

Signature: \_\_\_\_\_

  
Flemming Naundrup  
General Manager, Dameca a/s

Date of issue: 01 July 2016

Place of Issue: Roedovre, Denmark