

Declaration of Conformity

DAMECA

Revision: B
Tier: 4

Number: QSD4 -0018-F5
Element: Technical File

Quality System Document

Manufacturer: Dameca A/S
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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 name: Pressure Regulators and Reduction Valves
Description: Pressure Regulator and Reduction Valves for use with medical gas
Product Number (P\N): 33016, 33016-10, 33016-12, 33018, 33018-10, 33018-12,
33051, 33051c, 33062, 33063, 32576, 32577
GMDN code and Term: 35300 Regulator, high pressure gas
Device Classification and Rule: IIb, rule 9
Conformity Assessment Route: Annex II (full quality assurance)
Technical file reference: Tech file Index for Pressure Regulators and Reduction Valves

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