

## Declaration of Conformity

# DAMECA

Revision: B  
Tier: 4

Number: QSD4 -0018-F5  
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 name:** Medical Gas Channeling Units

**Description:** Medical Gas Channeling Units intended for channeling of medical gasses.

**Product Number (P\N):** See Attachment

**GMDN code and Term:** 36124 Medical gas supply system, component or terminal unit

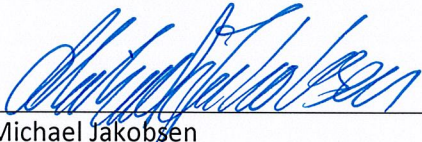
**Device Classification and Rule:** IIb, rule 11

**Conformity Assessment Route:** Annex II (full quality assurance)

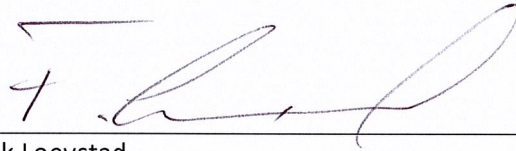
**Technical file reference:** Technical File Index for Medical Gas Channeling Units

### 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

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## Attachment

### Medical Gas Channeling Units - Product List

Gas Distributors Product Code	Couplings Product Code	Couplings Product Code	Plug Nipples Product Code
31079-00	31100F	31108	31202
31079A-00	31117C	31108C	31202A
31079B-00	31120	31110	31202B
31079C-00	31081	31110A	31202C
31080-00	31081B	31110B	31202G
31080A-00	31081C	31110C	31217
31080B-00	31081F	31110F	31217B
31080C-00	31100	31117A	31217C
30080-00	31100B	31120A	31203
30080B-00	31100C	31120F-120	31203B
30080C-00	31100D	31120G	31203C
30084-00	31117B	31120J	31203F
30084B-00	31117F	31303D	31202D
30084C-00	31120B	31303D-10	31202F
30124	31120C	31303D-40	31202J
30082-00	31120F	31303D-80	31203A
30082B-00	31081A		31203D
30082C-00	31081D		31203G
	31081G		31203G-10
	31081G-10		31203J
	31100A		31217A
	31100G		989803190821
	31100G-10		989803190831
	31117		989803190841