

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 name:

Respiration Valves

Description:

Respiratory and Berner Valves

Product Number (P\N):

11239, 12894, 12993C, 12994B

GMDN code and Term:

14337 Valve, positive end expiratory pressure

Device Classification and Rule:

IIb, rule 11

Conformity Assessment Route:

Annex II (full quality assurance)

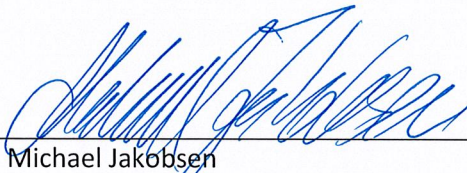
Technical file reference:

Technical File Index for Respiration 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

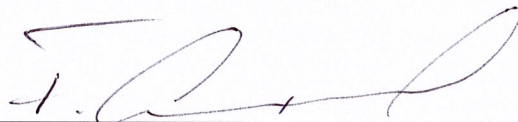
Date:

04 MARCH 2021

Place:

Roedovre, Denmark

Signature:



Frank Loevstad
CEO, Dameca A/S

Date:

5/3-2021

Place:

Roedovre, Denmark