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: Benveniste valve

Description: The Benveniste valve is intended to be used for Nasal CPAP treatment of neonatal patients and premature very low birth weight infants.

Product Number (P\N):

Product name	PN
Benveniste valve w/ pressure port	12082-01
Benveniste valve w/o pressure port	12083-01
Tube Connector 2,5mm	12083-02
Tube Connector 3,0mm	12083-03
Tube Connector 3,5mm	12083-04
Tube Connector 4,0mm	12083-05

GMDN code and Term: 36700 CPAP unit

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

Conformity Assessment Route: Annex II (full quality assurance)

Technical file reference: Technical File Index for Benveniste Valve

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: _____ Date: 04 MARCH 2021
Michael Jakobsen
Quality & Regulatory Manager, Dameca A/S
Place: Roedovre, Denmark

Signature: _____ Date: 5/3 - 2021
Frank Loevstad
CEO, Dameca A/S
Place: Roedovre, Denmark