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: Suction

Description: Removing secretions and blood from patients.

Product Number (P\N):

Product name	PN
Single high VAC regulator	32005-00
Single low VAC regulator	32006-00
Double high & low VAC regulator	32001-00
Single high ejector VAC regulator	32515-00

GMDN code and Term: 47367 Pneumatic emergency suction system

Device Classification and Rule: IIa, rule 11 of annex IX

Conformity Assessment Route: Annex II (full quality assurance)

Technical file reference: Technical File Index for Suction

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