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: Unisorb

Description: The absorber is intended to remove CO_2 from the patient breathing system

Product Number (P\N):

Product name	PN	Sales unit	Cone size
Unisorb disposable absorber	11056	NA	45 mm cone
	11056-15	15 pcs. box	
	11057	NA	50 mm cone

GMDN code and Term: 37022 Carbon dioxide absorber, reusable

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

Conformity Assessment Route: Annex II (full quality assurance)

Technical file reference: Tech File Index for Unisorb

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