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: i-SORB

Description: Absorber for removing exhaled carbon dioxide.

Product Number (P\N):

Product name	PN	Sales unit
i-SORB Disposable absorber	11044	NA
	11044-18	1 pcs. Box
	11044-08	8 pcs. Box
i-SORB Reusable absorber	11048	NA

GMDN code and Term: i-SORB Disposable absorber: 42414 Absorber, carbon dioxide, single use
i-SORB Reusable absorber: 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: Technical File Index for i-SORB

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