

# Declaration of Conformity

# DAMECA

Revision: B  
Tier: 4

Number: QSD4 -0018-F5  
Element: Technical File

Quality System Document

**Manufacturer:** Dameca A/S  
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**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<sub>2</sub> 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)

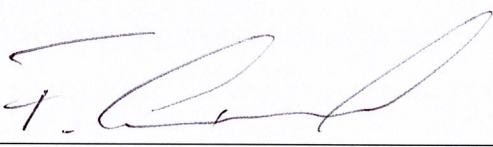
**Technical file reference:** Tech File Index for Unisorb

**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:**   
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

**Restricted**

QSD4-0003-F2 QMS Procedure Template – Rev A