

## Declaration of Conformity

# DAMECA

Revision: B

Number: QSD4 -0018-F5

Tier: 4

Element: Technical File

Quality System Document

**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	Anesthesia Workstation Siesta I
Product name:	Siesta I Whispa
Description:	Anesthesia Workstation
Product Number (P\N):	10651-00
Product name:	Dameca MRI508
Description:	Anesthesia Workstation
Product Number (P\N):	10651MRI-00
GMDN code and Term:	37710, Anesthesia Workstation, general-purpose
Device Classification and Rule:	IIb, Rule 11
Conformity Assessment Route:	Annex II
Technical file reference:	Technical File Index – Siesta i

**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:

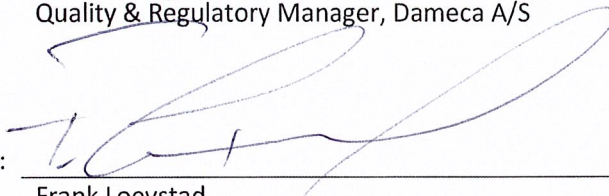


Michael Jakobsen  
Quality & Regulatory Manager, Dameca A/S

Date: 21 January 2021

Place: Roedovre, Denmark

Signature:



Frank Loevstad  
CEO, Dameca A/S

Date:

29/1-2021

Place: Roedovre, Denmark