

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 name:

Dameca AX500

Description:

Anesthesia Workstation, General Purpose

Product Number (P\N):

10621-00

GMDN code and Term:

37710 Anesthesia Workstation, General Purpose

Device Classification and Rule:

IIb rule 11

Conformity Assessment Route:

Annex II

Technical file reference:

Dameca AX500 Technical File Index

**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

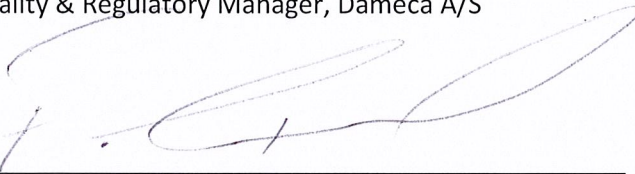
Date:

19 October 2020

Place:

Roedovre, Denmark

Signature:



Frank Loevstad
CEO, Dameca A/S

Date:

19/10 - 2020

Place:

Roedovre, Denmark