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: _____ Date: 19 October 2020
Michael Jakobsen
Quality & Regulatory Manager, Dameca A/S
Place: Roedovre, Denmark

Signature: _____ Date: 19/10-2020
Frank Loevstad
CEO, Dameca A/S
Place: Roedovre, Denmark