Declaration of Conformity

CE 0459

Manufacturer:

Dameca a/s,
Islevdalvej 211,
DK-2610 Roedovre, Denmark
Phone: +45 44509990

We the Manufacturer declare under our sole responsibility that the product:

Product family: Suction

Description: Removing secretions and blood from patients.

Product name	PN
Single high VAC regulator	32005-00
Single low VAC regulator	32006-00
Double high & low VAC regulator	32001-00
Single high ejector VAC regulator	32515-00

GMDN code and Term: 47367 Pneumatic emergency suction system

Device Classification and Rule: IIa, rule 11 of annex IX

Conformity Assessment Route: Annex II (full quality assurance)

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.

Notified Body: LNE/GMED, Rue Gaston Boissier; 75724 Paris Cedex 15, France
Identification number: 0459

EC Certificate no: 7789

Signature: _____ Date of issue: 01 July 2016

Peter Jørgensen
QA/RA Manager, Dameca a/s

Place of Issue: Roedovre, Denmark

Signature: _____ Date of issue: 01 July 2016

Flemming Naundrup
General Manager, Dameca a/s

Place of Issue: Roedovre, Denmark