



ATTESTATION / CERTIFICATE N° 7789 rev. 10
Délivrée à Paris le 07 avril 2020
Issued in Paris on April 7th, 2020

ATTESTATION CE / EC CERTIFICATE

Approbation du Système Complet d'assurance Qualité / Approval of full Quality Assurance System
ANNEXE II excluant le point 4 Directive 93/42/CEE relative aux dispositifs médicaux
ANNEX II excluding section 4 Directive 93/42/EEC concerning medical devices
Pour les dispositifs de classe III, un certificat CE de conception est requis
For class III devices, a EC design certificate is required

Fabricant / Manufacturer

DAMECA A/S
Islevdalvej 211
2610 RODOVRE DENMARK

Catégorie du(des) dispositif(s) / Device(s) category

Stations d'anesthésie (STA), Régulateurs de pression, Débitlitres, Valves respiratoires, Valves CPAP, Absorbours, Dispositif d'aspiration, Connecteurs, Système d'apport d'O2

Anaesthetic Workstations (AWS), Pressure Regulators, Flow Meters, Respiratory Valves, CPAP valves, Absorbers, Suction, Connectors, System Solutions

Voir détails sur addendum / See attachment for additional information

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P159929, P600876, le système d'assurance qualité - pour la conception, la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe II excluant le point 4 de la Directive 93/42/CEE.

GMED certifies that, on the basis of the results contained in the file referenced P159929, P600876, the quality system - for design, manufacturing, and final inspection - of medical devices listed here above complies with the requirements of the Directive 93/42/EEC, annex II excluding section 4

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / Effective date : **April 7th, 2020 (included)**

Valable jusqu'au / Expiry date : **May 26th, 2024 (included)**



On behalf of the President
Béatrice LYS
Technical Director

GMED_bap3F-VG-07-2018

GMED - 7789 rev. 10
Renouvelle le certificat 7789-9

GMED • Société par Actions Simplifiée au capital de 300 000 € • Organisme Notifié/Notified Body n° 0459
Siège social : 1, rue Gaston Boissier - 75015 Paris • Tél. : 01 40 43 37 00 • gmed.fr

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GROUPE LNE

Addendum à l'attestation N° 7789 rev. 10 page 1 / 7
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Identification des dispositifs / Identification of devices

Product Family: Dameca AX500

Description of the device / Accessories	Ref commercial CE marked device or item code	Class MD
Dameca AX500	10621-00	IIb

Product Family: IntelliSave AX700

Description of the device/ Accessories	Ref commercial CE marked device or item code	Class MD
IntelliSave AX700	10623-00	IIb

Product Family: Siesta i

Description of the device / Accessories	Ref commercial CE marked device or item code	Class MD
Siesta iTS	10653-00	IIb
Siesta i Whispa	10651-00	IIb
Dameca MRI508	10651MRI-00	IIb

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On behalf of the President
Béatrice LYS
Technical Director

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KOJIJA TIKIČA
 Direktorius
 Algis Bakutis

2022 -Ub- 3.0

Product Family: Pressure Regulators and Reduction Valves

Description of the device / Accessories	Ref commercial CE marked device or item code	Class MD
02 Reduction valve	33016 and 989803195051	IIb
AIR Reduction valve	33018 and 989803195061	IIb
02 Reduction valve, pin index with mini female outlet	33051	IIb
Combi Valve 02 for humidifier	33062	IIb
02 Reduction valve with flow meter gauge 0-15L/min	33063	IIb
Combined reduction valve w/ vacuum	32576-00	IIb
Combined reduction valve w. vacuum, pin index	32577	IIb
Reduction.Valve O2/Mini Female	33016-10	IIb
Reduction.Valve 02 w.Flow meter	33016-12	IIb
Reduction.Valve Air/Mini Female	33018-10	IIb
Reduction.Valve AIR w/ Flow meter	33018-12	IIb
AIR Reduction valve, pin index with mini female outlet	33051c	IIb

GMED 0459

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 Béatrice LYS
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On behalf of the President
Béatrice LYS
 Technical Director

GMED

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 Alg's tekum

2022-08-30

Product Family: Flow meter

Description of the device/ Accessories	Ref commercial CE marked device or item code	Class MD
O ₂ flow meter 1-15 L/min	32015-00	Ila
Air flow meter 1-16 L/min	32015C-00	Ila
Double O ₂ flow meter 1-15 L/min	32016-00	Ila
Double Air flow meter 1-16 L/Min	32016C-00	Ila
Combined O ₂ and Air flow meter O ₂ 1-15 L/min Air 1-16 L/min	32031-00	Ila

Product Family: i-SORB

Description of the device / Accessories	Ref commercial CE marked device or item code	Class MD
i-SORB Disposable absorber	11044	Ila
i-SORB Disposable absorber, 1pcs. Box	11044-18	Ila
i-SORB Disposable absorber, 8 pcs Box	11044-08	Ila
i-SORB Reusable absorber	11048	Ila
i-SORB Reusable absorber, 1 pcs Box	11048-1	Ila

Product Family: Unisorb

Description of the device/ Accessories	Ref commercial CE marked device or item code	Class MD
Unisorb Disposable absorber 45 mm	11056-15	Ila
Unisorb Disposable absorber 50mm	11057-15	Ila

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 Béatrice LYS
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On behalf of the President
Béatrice LYS
 Technical Director

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KO: IJATI KR
 Direktur
 Algis Bakus

2022-08-30

Product Family: Suction

Description of the device / Accessories	Ref commercial CE marked device or item code	Class MD
Plastic Cone Male 8mm Straight White	13640	Ila
Plastic Cone Female 8mm Straight White	13644	Ila
Double VAC w/ regulator	32001-00	Ila
Double VAC w/ regulator strong	32002-00	Ila
VAC regulator strong, single	32005-00	Ila
VAC regulator strong, single, MRI compatible	32005-mri	Ila
VAC regulator low, single	32006-00	Ila
Jet/ ejector VAC, strong	32515-00	Ila
Suction Tubing Set	32516-50	Ila

Product Family: Benveniste Valve

Description of the device / Accessories	Ref commercial CE marked device or item code	Class MD
Benveniste valve w/ pressure port.	12082-01	Ila
Benveniste valve w/o pressure port.	12083-01	Ila
Tube Connector 2,5mm	12083-02	Ila
Tube Connector 3,0mm	12083-03	Ila
Tube Connector 4,0mm	12083-04	Ila
Tube Connector 5,0mm	12083-05	Ila

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 Béatrice LYS
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On behalf of the President
Béatrice LYS
 Technical Director

GMED

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KOHLIATIKRA
Direktorius
Algis Bakula

2022-08-30

Product Family: Connector

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Description of the device / Accessories	Ref commercial CE marked device or item code	Class MD
Sliding clamp w/ 2 x 02 mini connector, horizontal	30080-00	IIb
Sliding clamp w/ 2 x VAC mini connectors, horizontal	30080b-00	IIb
Sliding clamp w/ 2 x AIR mini connectors, horizontal	30080c-00	IIb
Sliding clamp w/ 4 x 02 mini connectors	30084-00	IIb
Sliding clamp w/ 4 x VAC mini connectors	30084b-00	IIb
Sliding clamp w/ w/ 4 x AIR mini connectors	30084c-00	IIb
Double outlet, N2O, straight	31079A-00	IIb
Double outlet, N2O, angled	31080A-00	IIb
Double outlet, AGSS/WAGD, angled	31080F-00	IIb
Double outlet, O2, straight	31079-00	IIb
Double outlet, VAC, straight	31079B-00	IIb
Double outlet, AIR, straight	31079C-00	IIb
Double outlet, O 2, angled	31080-00	IIb
Double outlet, VAC, angled	31080B-00	IIb
Double outlet, AIR, angled	31080C-00	IIb

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Béatrice LYS
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On behalf of the President
Béatrice LYS
 Technical Director

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KOPĖLĖKRA
 Direktorius
 Algis B. Lius

2022 -08- 31

Description of the device / Accessories	Ref commercial CE marked device or item code	Class MD
Mini straight connection, 02	31202	IIb
Mini straight connection, N2O	31202A	IIb
Mini straight connection, VAC	31202B	IIb
Mini straight connection, AIR	31202C	IIb
Mini Male Nipple, CO2 (gen. 1)	31202G	IIb
Mini Male Nipple, CO2 (gen. 2)	31202G-10	IIb
Draeger angle connection, 02	31217	IIb
Draeger anale connection, VAC	31217B	IIb
Draeger angle connection, AIR	31217C	IIb
Angle connector w/ ISO ø22mm, cone	13982	IIb

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 Béatrice LYS
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On behalf of the President
Béatrice LYS
 Technical Director

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KOTIJA TIKRA
Direktorius
Algis Bakutis

2022 -08- 30

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Product Family: Respiration Valve

Description of the device/ Accessories	Ref commercial CE marked device or item code	Class MD
Respiration valve	11239	IIb
Berner Valve, Datex-Ohmeda	12894	IIb
Berner Valve, Swedish, ISO	12993C	IIb
Berner Valve, Danish, ISO	12994B	IIb

Ce certificat couvre le site et les activités suivantes
This certificate covers the following site and activities

DAMECA A/S - Islevdalvej 211 - 2610 Rødovre – DENMARK :
 Conception, fabrication et contrôle final / Design, manufacture and final control

GMED 0459

On behalf of the President
Béatrice LYS
 Technical Director

AMTAC
Intertek
Aigis Bakutis



2022-08-30

Certificate Number
610-CE-2018

Initial Certification Date
12 November 2021

Certificate Issue Date
14 March

Certificate Expiry Date
11 November 2023

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

This Certificate is for the exclusive use of AMTAC's client and is provided pursuant to the agreement between AMTAC and its Client. AMTAC's responsibility and liability are limited to the terms and conditions of the agreement. AMTAC assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate. Only the Client is authorized to permit copying or distribution of this Certificate. Any use of the AMTAC name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by AMTAC.

AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473

*AMTAC Certification Services Limited
Davy Avenue
Knowlhill
Milton Keynes
MK5 8NL, UK
Telephone
+44 (0)1908 857 750
Email acsl@intertek.com*

EC Certificate

PRODUCTION QUALITY ASSURANCE
Directive 93/42/EEC for Medical Devices, Annex II (OBL.)

We hereby declare that an examination of the under mentioned production quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II of the Directive 93/42/EEC on medical devices via an Own Branding arrangement. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0473 marking on those products listed below.

Organization:

VERSAMED INC

2 Blue Hill Plaza, PO Box 1512, Pearl River, NY 10965, USA

Computerized Ventilator systems:
iVent 201 [iVent 2011C, iVent 201AB, iVent 201C and AB,
iVent 201 HC, iVent 201HS]
iVent 101

Authorized Signatory:

AMTAC Certification Services Limited, Milton Keynes, UK



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Declaration of Conformity

According to ISO/IEC 17050

**Manufacturer's Name & Address:**

FUJIFILM SonoSite, Inc.
21919 30th Drive SE
Bothell, Washington 98021-3904 USA

European Authorized Representative's Name & Address:

FUJIFILM SonoSite B.V.
Joop Geesinkweg 140
1114 AB, Amsterdam, The Netherlands

Declares that the CE-marked product(s):

Item	Classification	Part Number(s)	GMDN Code
Bar Code Scanner Kit	Rule 1	P14166	37035
Battery	Rule 1	P15051	36534
Bite Hole Indicator Meter Kit	Rule 1	P20870	36796
ECG Cable and Leadwires	Rule 1	P01592, P03241	35562
ECG Slave Cable and Adapter Kit	Rule 1	P20262	35562
Edge Mini-Dock	Rule 1	P15078	17115
Edge Stand	Rule 1	P15800	40596
EU-Compliant Wireless Kit	Rule 1	P21701	32547
Power Supply	Rule 1	P09823	36545
PowerPack	Rule 1	P13122	17115
PowerPark Dock	Rule 1	P12834	17115
PowerPark Stand Module	Rule 1	P12822	40596
Triple Transducer Connect	Rule 1	P16535	62345
Wireless Kit	Rule 1	P17726	32547
SiteLink Image Manager	Rule 12	P10117	40829

Complies with:

European Community Council Directive (Medical Device Directive) 93/42/EEC as amended by 2007/47/EC, Annex VII, and are Class I medical device accessories in accordance with Annex IX, Rule 1 and Annex IX, Rule 12. MDD compliance is assured under the sole responsibility of the manufacturer.

Directive 2011/65/EU (RoHS2 Directive) of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast) in accordance with Annex I, Category 8. RoHS compliance is assured under the sole responsibility of the manufacturer.

Standards Applied:

- EN IEC 60601-1:2006, 3rd Edition, Am 1:2013
- EN IEC 60601-2-37:2008
- EN IEC 60601-1-2:2007
- EN ISO 14971:2012
- EN 50581:2012

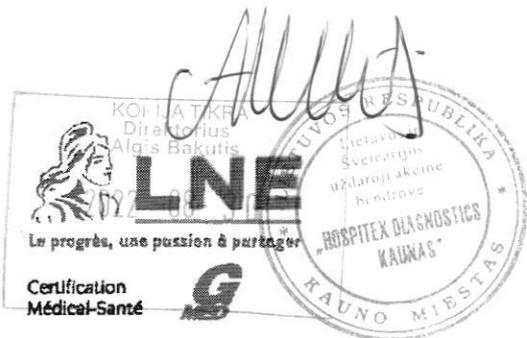
Quality Management and Quality Assurance:

- ISO 9001:2008, Quality management systems -- Requirements International Organization for Standardization
- ISO 13485:2003, Medical devices – Quality management systems – Requirements for regulatory purposes
- EN ISO 13485:2012, Medical devices – Quality management systems – Requirements for regulatory purposes

Date CE mark was first applied: December 18, 2015

November 8, 2017
Bothell, Washington USA

Scott Paulson
Sr. Director, Regulatory Affairs and Quality Systems



**CERTIFICAT
CERTIFICATE OF REGISTRATION
N° 31051 rev. 0**

**Le LNE certifie que le système de management de la qualité développé par
LNE certifies that the quality management system developed by**

MEDIPREMA

**470 rue Gilles de Gennes Zone d'Activité Node Park Touraine
37310 TAUXIGNY FRANCE**

**pour les activités
for the activities**

**Conception, fabrication, vente et entretien de dispositifs médicaux pour la néonatalogie,
périnatalogie, pédiatrie et l'obstétrique.**

**Design, manufacturing, sales and maintenance of medical devices for neonatology,
perinatology pediatrics and obstetrics.**

**réalisées sur le(s) site(s) de
performed on the location(s) of**

**MEDIPREMA
470 rue Gilles de Gennes - Zone d'Activité Node Park Touraine 37310 TAUXIGNY FRA**

**est conforme aux exigences des normes internationales
complies with the requirements of the international standards**

ISO 13485 : 2003

**Début de validité / Effective date : March 27th, 2016 (Included)
Valable jusqu'au / Expiry date : February 28th, 2019 (included)
Etabli le / Issued on : March 23rd, 2016**

cofrac



COFRAC
COFRAC 2014-2018
CERTIFICATION
DE SYSTEMES
DE MANAGEMENT
Accréditation n°4-0036
Liste des sites accrédités
et portés disponibles sur
www.cofrac.fr

LNE N° 31051-0
Ce certificat est délivré selon les règles de certification G-MED / This certificate is issued according to the rules of G-MED certification
LNE/G-MED Organisme notifié pour les Dispositifs Médicaux / LNE/G-MED Notified Body for Medical Devices
Renouvele le certificat 7680-5



**On behalf of the Certification Director
Cécile VAUGELADE
G-MED Certification Division Manager**

**Laboratoire national de métrologie et d'essais - Établissement public à caractère industriel et commercial
LNE/G-MED - Organisme notifié n° 0459
1, rue Gaston Boissier - 75724 Paris Cedex 15 - Tél. : 01 40 43 37 00 - Fax : 01 40 43 37 37 - www.lne.fr - www.gmed.fr**



EB Neuro S.p.A.

Sede Legale e Commerciale
Registered Office and Sales Department
Via P. Fanfani, 97/A - 50127 Firenze - ITALY
Phone +39 055 4565111 - Fax +39 055 4565123
ebn@ebneuro.com - www.ebneuro.com
Partita IVA / V.A.T. Number 04888840487



DICHIARAZIONE DI CONFORMITA' DECLARATION OF CONFORMITY

Costruttore/Manufacturer:
EB Neuro S.p.A.
Via P. Fanfani, 97/A
50127 - Firenze - Italia

Dispositivi Medici/Medical Devices: GALILEO MIZAR
Nome Modello/Model Name:

Codici identificativi/Reference codes : **B9800082000**

Classific. EN/IEC: **Classe IIb**
Tipo BF (ingressi paziente)

Il costruttore dichiara che i Dispositivi Medici (apparecchi/sistemi elettromedicali), come sopra specificato e le relative opzioni, sono conformi alle seguenti norme armonizzate:
The manufacturer declares that the Medical Devices (electromedical equipments/systems), as specified above and the related options, are in conformity with the following harmonized standard:

Standard Ref.	Title	CEI Classification
EN 60601-1:1991 (Ed. 2) + A1:1993 + A2:1995	Medical Electrical Equipments, general Safety Standard	CEI 62-5
EN 60601-1-1:2001 (Ed. 2)	Medical Electrical Systems, collateral Safety Standard	CEI 62-51
EN 60601-1-2:2001 (Ed. 2) + A1:2006	Medical Electrical Equipments, collateral Safety Standard Electromagnetic Compatibility	CEI 62-50
EN 60601-1-4:1996 (Ed. 1) + A1:1999	Programmable Medical Devices, Safety Standard	CEI 62-81
EN 60601-1-6:2004 (Ed. 1)	Medical Electrical Equipments, collateral Safety Standard Usability	CEI 62-138
EN 60601-2-26:2003 (Ed. 2)	Electroencephalographs, particular Safety Standard	CEI 62-61
EN 980:2008 (Ed. 2)	Symbols for use in the labelling of medical devices	CEI 62-149
EN ISO 9919:2009	Particular Requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.	/

Prima emissione/First issue (Rev.A): 30/07/2017

Il legale rappresentante
Authorized officer

Marco Rossi



EB Neuro S.p.A.
Via P. Fanfani, 97/A
50127 Firenze
P. IVA 04888840487

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