

## 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, Absorbants, 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

Le LNE/G-MED atteste qu'à l'examen des résultats figurant dans le rapport référencé P159929, 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.

*LNE/G-MED certifies that, on the basis of the results contained in the file referenced P159929, 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 : October 19th, 2017 (included)**

**Valable jusqu'au / Expiry date : September 11th, 2020 (included)**



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

**Identification des dispositifs / Identification of devices :**

**French version :**

**Stations d'anesthésie (STA), Régulateurs de pression, Débitlitres, valves respiratoires, Valves CPAP, Absorbants, Dispositif d'aspiration, connecteurs, système d'apport d'O2.**

**English version :**

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

**Les produits couverts par ce certificat sont référencés sur la liste des produits (5 pages) authentifiée par le LNE/G-MED le 19 octobre 2017 / The products covered by this certificate are listed on the manufacturer's list of products (5 pages) authenticated by LNE/G-MED on October 19, 2017.**

**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**

<b>LNE/G-MED</b>	<b>0459</b>
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**On behalf of the Certification Director  
Cécile VAUGELADE  
G-MED Certification Division Manager**

**PRODUCT SCHEDULE FOR CERTIFICATE No 7789**

**Manufacturer: Dameca A/S**

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

Product Family: Pressure Regulators and Reduction Valves

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

LNE/G-MED (0459) reconnaît que son certificat CE est valide pour les dispositifs médicaux décrits

19 OCT. 2017

LNE/G-MED (0459) recognizes that its EC certificate is valid for the medical devices listed

PERON  




**PRODUCT SCHEDULE FOR CERTIFICATE No 7789**

**Manufacturer: Dameca A/S**

Product Family: Flow meter

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

Product Family: I-SORB

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


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	IIb
Unisorb Disposable absorber 50 mm	11057-15	IIb

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**PRODUCT SCHEDULE FOR CERTIFICATE No 7789**

**Manufacturer: Dameca A/S**

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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**PRODUCT SCHEDULE FOR CERTIFICATE No 7789**

**Manufacturer: Dameca A/S**

Product Family: Connector

Description of the device / Accessories	Ref commercial CE marked device or item code	Class MD
Sliding clamp w/ 2 x O2 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 O2 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, O2, angled	31080-00	IIb
Double outlet, VAC, angled	31080B-00	IIb
Double outlet, AIR, angled	31080C-00	IIb
Mini straight connection, O2	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, O2	31217	IIb
Draeger angle connection, VAC	31217B	IIb
Draeger angle connection, AIR	31217C	IIb
Angle connector w/ ISO ø22mm, cone	13982	IIb

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**PRODUCT SCHEDULE FOR CERTIFICATE No 7789**

**Manufacturer: Dameca A/S**

Product Family: Respiration Valve

Description of the device / Accessories	Ref commercial CE marked device or item code	Class MD
Respiration valve	11239	IIb
Respiration valve, COAX, ISO	12964	IIb
Berner Valve, Datex-Ohmeda	12894	IIb
Berner Valve, Swedish, ISO	12993C	IIb
Berner Valve, Danish, ISO	12994B	IIb
Emergency O2 by-pass valve	11046	IIb

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