Medical Device Application

ARTG No : 221447

Class IIb
Status : Approved

Application Change history

Active medical device for therapy. Class IIb according to classification rule 4.2(2). Intended purpose is clear and consistent with the device product charactersitics and the GMDN code. Appears to be covered under the scope of full quality assurance certificate as medical pressure regulator (Jessica Solomon, 18/03/2014)

Application Progress Date	
Date received:	13/03/2014

Review Information	
Review flag:	
Auto review required:	No

Device Product Characteristics

Is the device, or any form of the device, supplied sterile: No
Is the device intended to be invasive: No
Is the device, or any form of the device, intended for single use: No
Is the device an active device: Yes
Does the device contain material or ingredients of microbial origin: No
Does the device contain material or ingredients of recombinant origin: No
Does the device contain material or ingredients manufactured or formulated using a genetically modified organism: No
Does the device contain material or ingredients of Human Origin: No
Does the device consist of: Single product only
Does the device contain material or ingredients of Animal Origin rendered non-viable: No
Is the device medicated: No
Does the product contain a medicine that is supplied separately in the Australian Market: No
Does the product contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device: No

Application Summary	
Application ID:	DV-2014-DA-04155-1
Submission ID:	DA-2014-01795-1
Sponsor's own reference:	Rotarex Gas Pressure Regulator
Application for:	Medical Device - Included
Will you be applying for listing of this product or procedure in the Medicare Benefit Schedule (MBS)?	○ Yes ○ No
Will you be applying for listing	○ Yes ○ No

of this product on the Prosthesis List?	
Will you be applying for listing of this product on the Co-dependent or hybrid technology application list?	○ Yes ○ No
Sponsor name:	Rotarex Australia / New Zealand Pty Ltd
Sponsor ID:	58352
Agent name:	
Contact details :	Mark Prew
Contact email:	prew.mark@rotarex.com

Manufacturer Information

Manufacturer's evidence:	DV-2012-MC-19773-1 :SMT - Medical Gas Regulators Goto
Manufacturer name:	SMT SAS (France)[48665]
Assessment route:	Council Directive 93/42/EEC (MDD)
Assessment body:	Apragaz A.S.B.L [0029]
GMDN code:	Oxygen cylinder regulator[43438]
GMDN description:	A reduction valve designed to be attached through a gastight connector (e.g., a pin-index or bull-nosed screw thread connection) to the valve stem of an oxygen (O2) cylinder to lower high, variable gas pressure (e.g., 50 - 250 bar) to a lower, constant working pressure, typically 3 - 5 bar. It can be a single or a dual stage regulator, usually of a piston or diaphragm design. It will have a safety relief valve to avoid excessive pressure due to increased ambient temperatures, and it may have associated devices, usually a manometer or manometers, to display the available gas reserve of a gas cylinder and the working pressure
Intended purpose :	Provide a regulated medical gas flow from a high pressure gas source to patient.

Device Category Terms

Device category 1:	Anaesthetic and respiratory devices

Attached Documentation

EC Certificate - 03_FR_607-9-Rev0-Dir 93-42-EC_(Amd 2007-47-EC)-Medical Devices.pdf

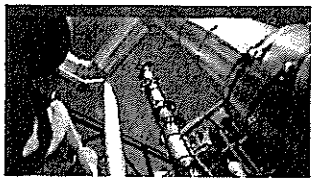
History

19/03/2014 8:03:37 AM Approved.

Review Completed - Accepted, 19/03/2014)

Record	Date	
Fee:	Date Paid:	14/03/2014
	Date Decision:	18/03/2014

Start Dates		Finish Dates		Working Days
Application Received	13/03/2014	Payment Received	14/03/2014	1
			Total Working Days	1



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BELAC EN ISO/IEC 17021 Cert N° 084-QMS

NOTIFIED BODY EC CERTIFICATE OF CONFORMITY In accordance with Appendix II (excl. par. 4) of the Medical Devices Directive 93/42/EC (Amd. 2007/47/EC)		Certificate N° 03/FR/607-9-REV0 Page 1/4
Manufacturer	Name	**SMT S.A.S.** **5, Rue de Labergement** **F-21110 Genlis** **FRANCE**
	Address	
Production facilities	Name	**SMT S.A.S.** **5, Rue de Labergement** **F-21110 Genlis** **FRANCE**
	Address	

Concerned Equipment: See page 2/2

This is to certify that the Quality Management System of the above mentioned manufacturer has been assessed against the requirements of Appendix II (- par. 4) of the Medical Devices Directive 93/42/EC (Amd. 2007/47/EC) and conforms to the requirements for the equipment shown above. The approval is subject to the continued maintenance of the Quality System in accordance with the requirements of the above Directive, this shall be controlled by intermediate audits, inspections and surveys.

The manufacturer is allowed to affix the "CE" mark followed with our notified body identification number 0029 to the approved equipment in the conditions described in the Directive.

The approval is valid is mentioned on pages 2/3 and 3/3 here after.

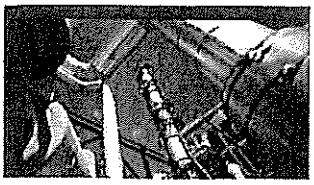
Date : 22/11/2013 Name : **Ch. Leplat** Position **General Manager**

Notified body identification number : **0029**

Signature

Notified body stamp : **APRAGAZ Belgium Inspecting Authority**

Notified body reference : **0307/P6161**



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BELAC EN ISO/IEC 17021 Test N° 084-CMS

NOTIFIED BODY EC CERTIFICATE OF CONFORMITY

In accordance with Appendix II (excl. par. 4) of the Medical Devices Directive 93/42/EC (Amd. 2007/47/EC)

Certificate N° 03/FR/607-9-REV0

Products concerned :

Medical Pressure Regulator					
Reference	Gas	Maximum Working Pressure	Applicable Standard	Temperature range	Validity date
Automatic Switchover CEN 10	O_2, N_2, N_2O, CO_2,He, Xe, medical air or other mixtures of these gases	P. inlet: 200 bar P. outlet: 10 bar	EN ISO 10524-2	-20°C/+60°C	22.11.2018
Module of régulation CEN 10	O_2, N_2, N_2O, CO_2,He, Xe, medical air or other mixtures of these gases	P. inlet: 200 bar P. outlet: 10 bar	EN ISO 10524-2	-20°C/+60°C	22.11.2018
DI235	NO / N_2 (less than 1000 ppm NO)	P. inlet: 200 bar / 300 bar P. outlet: 2,5 bar / 5 bar	EN ISO 10524-1	-20°C/+60°C	22/11/2018
DM 20	O_2, N_2, Air	P. inlet: 20 bar P. outlet: 10 bar / 12 bar	EN ISO 10524-2	-20°C/+60°C	07/06/2018
DM 20GD	O_2, N_2, Air	P. inlet: 20 bar P. outlet: 10 bar / 12 bar	EN ISO 10524-2	-20°C/+60°C	07/06/2018
DM 200 GD	O_2, N_2, Air	P. inlet: 20 bar P. outlet: 0 - 20 bar	EN ISO 10524-2	-20°C/+60°C	22/11/2018
DM 200 TGD	O_2, N_2, Air	P. inlet: 20 bar P. outlet: 10 bar / 12 bar	EN ISO 10524-2	-20°C/+60°C	07/06/2018
HCR 25	O_2, N_2, N_2O, CO_2,He, Xe, medical air or other mixtures of these gases	P. inlet: 200 bar P. outlet: 3,5 bar	EN ISO 10524-1	-20°C/+60°C	26/04/2018
HBSI 240-5	NO/ N_2	P. inlet: 200 bar P. outlet: 5 bar	EN ISO 10524-1	-20°C/+60°C	22.11.2018
HBSI 240-8	NO/ N_2	P. inlet: 200 bar P. outlet: 0,5-8 bar	EN ISO 10524-1	-20°C/+60°C	22.11.2018

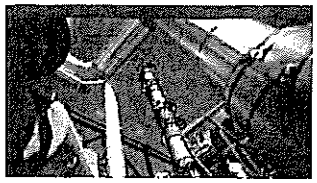
Date : 22/11/2013 Name : Ch. Leplat Position General Manager

Notified body identification number : 0029

Signature

Notified body stamp : APRAGAZ Belgium Inspecting Authority

Notified body reference : 0307/P6161



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BELAC EN ISO/IEC 17021 Cert. N° 084-ERS

NOTIFIED BODY EC CERTIFICATE OF CONFORMITY

In accordance with Appendix II (excl. par. 4) of the Medical Devices Directive 93/42/EC (Amd. 2007/47/EC)

Certificate N° 03/FR/607-9-REV0

Products concerned :

Medical Pressure Regulator					
Reference	Gas	Maximum Working Pressure	Applicable Standard	Temperature range	Validity date
Central ECOGAZ AR215-110	O_2, N_2, N_2O, CO_2,He, Xe, medical air or other mixtures of these gases	P. inlet: 200 bar P. outlet: 15 bar	EN ISO 10524-2	-20°C/+60°C	22.11.2018
Module ECOGAZ AR215-110	O_2, N_2, N_2O, CO_2 or other mixtures of these gases	P. inlet: 200 bar P. outlet: 15 bar	EN ISO 10524-2	-20°C/+60°C	22.11.2018
Kit Duobloc ECOGAZ AR215-110	O_2, N_2, N_2O, CO_2,He, Xe, medical air or other mixtures of these gases	P. inlet: 200 bar P. outlet: 15 bar	EN ISO 10524-2	-20°C/+60°C	22.11.2018
SCL 290/390	O_2, N_2, N_2O, CO_2, Air	P. inlet: 200 / 300 bar P. outlet: 4 bar	EN ISO 10524-1	-40°C/+60°C	27/07/2018
SCL 291/391	O_2, N_2, N_2O, CO_2, Air	P. inlet: 200 / 300 bar P. outlet: 8 bar	EN ISO 10524-1	-40°C/+60°C	27/07/2018

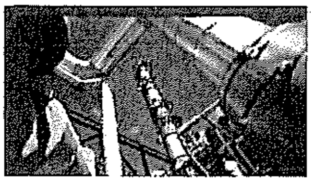
Date : 22/11/2013 Name : Ch. Leplat Position General Manager

Notified body identification number : 0029

Signature

Notified body stamp : APRAGAZ Belgium Inspecting Authority

Notified body reference : 0307/P6161



Document 5

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BELAC EN ISO/IEC 17021 CERT N° 084-QMS

NOTIFIED BODY EC CERTIFICATE OF CONFORMITY In accordance with Appendix II (excl. par. 4) of the Medical Devices Directive 93/42/EC (Amd. 2007/47/EC)	Certificate N° 03/FR/607-9-REV 0 Page 4/4

Products concerned :

Medical Equipments					
Reference	Gas	Maximum Working Pressure	Applicable Standard	Temperature range	Validity date
ALPISWITCH M820	O_2, N_2, N_2O, CO_2, and medical air	P. inlet: 200 bar P. outlet: 10 bar	EN ISO 10524-2 EN ISO 10524-3 EN ISO 10297	-20C / +60°C	05/02/2018
ALPISWITCH M825	O_2, N_2, N_2O, CO_2, and medical air	P.inlet: 200 bar P. outlet: 8 -10 bar	EN ISO 10524-2 EN ISO 10524-3 EN ISO 10297	-20C / +60°C	05/02/2018
ALPIREG 2 M840	O_2, N_2, N_2O, CO_2, and medical air	P. inlet: 10 bar P. outlet: 4.5 bar	EN ISO 10524-2 EN ISO 10297	-20C / +60°C	06/06/2018
ALPIREG 1 M845	O_2, N_2, N_2O, CO_2, and medical air	P. inlet: 10 bar P. outlet: 4.5 bar	EN ISO 10524-2 EN ISO 10297	-20C / +60°C	06/06/2018
ALPIMSV M850	O_2, N_2, N_20, CO_2, and medical air	10 bar	EN ISO 10297	-20C / +60°C	17/12/2017
ALPISAFE M830	O_2, N_2, N_2O, CO_2, and medical air	P. inlet: 200 bar P. outlet: 7 bar	EN ISO 10524-2 EN ISO 10524-3 EN ISO 10297	-20C / +60°C	17/12/2017
ALPI-LINK M858	O_2, N_2, N_2O, CO_2, and medical air	200 bar	EN ISO 21969	-20C / +60°C	23/04/2018
ALPI-MULTI M859	O_2, N_2, N_2O, CO_2, and medical air	200 bar	EN ISO 21969	-20C / +60°C	23/04/2018

Non return valves					
Reference	Gas	Maximum Working Pressure	Applicable Standard	Temperature range	Validity date
CAR M855	O_2, N_2, N_2O, CO_2, and medical air	25 bar	EN ISO 10524-2 EN ISO 7396-1	-20C / +65°C	25/03/2018
ALPI-NRV AF10	O_2, N_2, N_2O, CO_2, and medical air	200 bar	EN ISO 10524-2 EN ISO 10297	-20C / +60°C	23/04/2018

Date : 22/11/2013 Name : Ch. Leplat Position General Manager

Notified body identification number : 0029

Signature

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