



Manufacturer Evidence

Status : Versioned

Certificate change history

Date received : 21/01/2013

Certificate printed : No

New Notification

Notification details

Evidence identifier: DV-2013-MC-00916-1

Submission identifier: DM-2013-00397-1

Version number: 1

Sponsor's own reference: CEODEUX S.A. - Medical Intergrated Cylinder Valve

Sponsor details

Agent name:

Sponsor name: Rotarex Australia / New Zealand Pty Ltd

Contact details: Mark Prew - +61294776864 - prew.mark@rotarex.com

Certification details

Manufacturer name: Ceodeux SA (Luxembourg)[58472]

Manufacturer address as on certification: Route de Diekirch 24 -BP 19 Lintgen Grand Duche De Luxembourg LU-7505 L

Type of product:

This certification is to support an application for a medical device that is not an in vitro diagnostic medical device (IVD)

Certificate issued under: 02

Conformity assessment procedure: Schedule 3 Part 1 (Annex II)

Source of certification: Apragaz A.S.B.L [0029]

Certificate number: 03/LU/634-21-REV 0

Certificate issue date: (dd/mm/yyyy) 24/04/2012

Certificate expiry date: (dd/mm/yyyy) 10/06/2013

Certificate re-issue date: (dd/mm/yyyy)

Restrictions on scope:

Restriction on conformity assessment procedure:

Full Quality Assurance Certificate.

Note: For Class III a Design Examination Certificate must be submitted with the Device Application.

Attached documentation:

Attached documents

 EC Certificate - MEDITEC_03-LU-634-21_REV0.pdf

Supporting documents:

#	Document Type	Description	Method

Related Active ARTG Entry Information:

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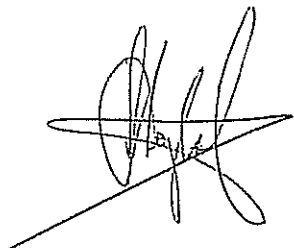
History

CN=Jessica Solomon/OU=TGA/O=Health



Chaussée de Vilvorde, 156
Vilvoordsesteenweg 156
B-1120 Bruxelles/Brussel
Tel.: 32 (0)2 264 03 60
Fax: 32 (0)2 268 89 58
<http://www.apragaz.com>
info@apragaz.com



NOTIFIED BODY EC CERTIFICATE OF CONFORMITY In accordance with Appendix II of the Medical Devices Directive 93/42/EC and it's latest amendment 2007/47/EC		Certificate N° 03/LU/634-21-REV 0 Page 1/3
Manufacturer	Name	CEODEUX S.A.
	Brand name	MEDITEC Route de Diekirch, 24 - B.P. 19 LU - 7505 Lintgen GRAND DUCHE DE LUXEMBOURG
Concerned Equipment: High pressure gas cylinder valves See details on pages 2/3 & 3/3 here after		
This is to certify that the Quality Management System of the above mentioned manufacturer has been assessed against the requirements of Annex II of the Medical Devices Directive 93/42/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 approved equipment in the conditions described in the Directive. The approval is valid until 10/06/2013		
Date : 24/04/2012	Name : Ch. Leplat	Position : General Manager
Notified body identification number :	0029	Signature
Notified body stamp :	APRAGAZ Belgium Inspecting Authority	
Notified body reference :	0306/P6123/ZMDD01	

**APRAGAZ**Member of
CEOC
INTERNATIONAL

Chaussée de Vilvorde, 156
Vilvoordsesteenweg 156
B-1120 Bruxelles/Brussel
Tel.: 32 (0)2 264 03 60
Fax: 32 (0)2 268 89 58
<http://www.apragaz.com>
info@apragaz.com

**NOTIFIED BODY EC CERTIFICATE OF CONFORMITY**

In accordance with Appendix II of the Medical Devices Directive
93/42/EC and it's latest amendment 2007/47/EC

Certificate N°
03/LU/634-21-REV 0
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Products concerned :

Product identification	Product description	According to standard
D113	High pressure cylinder valve for medical gases	EN ISO 10297 EN ISO 15996
D252	NO/N ₂ mixtures with an O.P. lower than air	EN ISO 10297
D413	High pressure cylinder valve	EN ISO 10297
D994	Adapter connection for mixtures N ₂ + NO	EN ISO 10297 ISO 5145
M040/M045	High pressure cylinder valve for medical carbon dioxide gases	EN ISO 10297
M100/M105	High pressure cylinder valve for medical oxygen gases	EN ISO 10297 TRG 770
M200/M205	High pressure cylinder valve for medical gases	EN ISO 10297 TRG 770
M500	High pressure cylinder valve CO ₂ with or without RPV	EN ISO 10297
M505	High pressure cylinder valve CO ₂ with or without RPV	EN ISO 10297
M508	High pressure cylinder valve CO ₂ with RPV	EN ISO 10297 EN ISO 15996
M510/M520	High pressure brass cylinder valve with RPV	EN ISO 10297 EN ISO 15996
M511	High pressure cylinder valve, for medical oxygen	EN ISO 10297 EN ISO 15996
M516	High pressure cylinder valve, for medical oxygen	EN ISO 10297 EN ISO 15996
M521	High pressure cylinder valve, for medical gases	EN ISO 10297 EN ISO 15996
M526	High pressure cylinder valve, for medical gases	EN ISO 10297 EN ISO 15996
M530	High pressure cylinder valve, for medical gases	EN ISO 10297
M540	High pressure cylinder valve, for medical oxygen	EN ISO 10297

(*) Technical files submitted for amendment 2007/47/EC extension

Date : 24/04/2012

Name : Ch. Leplat

Position General Manager

Notified body identification
number :

0029

Signature

Notified body stamp :

APRAGAZ
Belgium
Inspecting
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Notified body reference :

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Products concerned :

Product identification	Product description	According to standard
M650 (*)	Pin Index valve with residual pressure function, for all medical gases	EN ISO 10297
M705 (*)	High pressure brass cylinder valve, O-Ring Type, with integrated regulator, and flow meter for medical oxygen use (Standard design) <i>Remarks :</i> With RPV in connection with bottle 90-102.825 CEE Invacare Product One standard version One version with guard One version without check valve in the filling port	EN ISO 10524-3 CGA-V9
M706 (*)	High pressure brass cylinder valve, O-ring Type, with integrated regulator, and flow meter, (with flow regulator disc of 0.1mm), for medical oxygen use and pressure outlet.	EN ISO 10524-3 CGA-V9
M706 EZ-OX		
M711	High pressure brass cylinder valve with integrated regulator (300 bar/4,5 bar) for medical oxygen use <i>Remarks : with residual pressure valve</i>	EN ISO 10524-3 EN ISO 10297
M730	Medical pressure regulator with flow meter for medical Oxygen with pressures 200 bar / 3 bar	EN ISO 10524-1
M735	Medical pressure regulator with flow meter for O ₂ , N ₂ , Co ₂ , N ₂ O, He, Xe, air with pressures 200 bar / 3,5 bar	EN ISO 10524-1
M742	High pressure brass cylinder valve, O-Ring Type, with integrated regulator and flow meter for medical Oxygen use (300 bar / 4,5 bar)	EN ISO 10524-3
M830 - APLISAFE	Emergency central supply system for hospital and sanatoriums (200 bar / 7 bar) for medical gases (nominal flow 50 Nm ³ / h)	EN ISO 10524-2 EN ISO 7396-1
M840 - APLIREG 2	Single and double line regulators for hospitals (8 - 10 bar / 4 bar) for medical gases (O ₂ , Air, N ₂ O , Co ₂ , and medical mixtures)	EN ISO 10524-2 EN ISO 7396-1
M845 - APLIREG 1	Single and double line regulators for hospitals (8 - 10 bar / 4 bar) for medical gases (O ₂ , Air, N ₂ O , Co ₂ , and medical mixtures)	EN ISO 10524-2 EN ISO 7396-1
M850 - APLIMSV	Main section valve to connect Apliswitch, Aplisafe and mobile source for hospital gas supply system (20 bar) (O ₂ , Air, N ₂ O , Co ₂ , and medical mixtures)	EN ISO 10297 EN ISO 7396-1
M966 (*)	Pin Index valve for all medical gases	EN ISO 10297
M969	Small cone valve	EN ISO 10297
M970	Small cone valve	EN ISO 10297
M971	Small cone valve	EN ISO 10297
M972	Pin Index valve for all medical gases, O-Ring Type	EN ISO 10297
M973	Small cone valve	EN ISO 10297
M974	Pin Index valve for all medical gases, O-Ring type	EN ISO 10297
M975	Small cone valve	EN ISO 10297
M978	Cylinder valves small inlet connection for oxygen	EN ISO 10297
M979	Cylinder valves small inlet connection for miscellaneous gases	EN ISO 10297

(*) Technical files submitted for amendment 2007/47/EC extension

Date : 24/04/2012

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