



Medical Device Application

ARTG No : **205800**

Class IIb Status : Approved

Application Change history

Application Progress Date

Date received: 29/01/2013

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-2013-DA-01368-2

Submission ID: DA-2013-00600-1

Sponsor's own reference: M70600164 INTEGRATED MEDICAL VALVE

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 of this product on the Prosthesis List? Yes No

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-2013-MC-00916-1 :CEODEUX S.A. - Medical Intergrated Cylinder Valve Goto

Manufacturer name: Ceodeux SA (Luxembourg)[58472]

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 high pressure gas source to patient.

Device Category Terms

Device category 1: Anaesthetic and respiratory devices

Attached Documentation

-  Additional supporting documentation - M70600164.pdf
-  Additional supporting documentation - 164-5515.pdf

History

8/02/2013 10:07:37 AM Approved.

Review Completed - Accepted, 8/02/2013)

Record	Date		
Fee:	890	Date Paid:	30/01/2013
		Date	08/02/2013
		Decision:	

Start Dates	Finish Dates		Working Days	
Application Received	29/01/2013	Payment Received	30/01/2013	1
Payment Received	30/01/2013	Application Decision	08/02/2013	8
			Total Working Days	9

**Ceodeux S.A. - Meditec**

Part number:	M70600164	Customer :	
Drawing:	164-5515	Customer ref.:	
Working pres. :	3000 PSI	Inlet thread :	25E
Serie :	M706	Filling port standard :	CGA577
Gas service :	Medical O2	Material :	Brass chrome plated
Pressure outlet :	65 PSI	Dip tube :	yes

Pos.	Lev.	Article	Drawing	Qty	Description	Basic Material	Remarks
1	-2	050323555	135-5515-1	1	CORPS/M706/JS/LT/CHR/295A-B -G75	CW617N-H080(CuZn 40Pb2)	butée usinée
2	-3	051300013	2-4925-130c	1	PASTILLE M705 PA6.6 ØE9.1 Ø4.4 H3.4	ZYTEL E50 / ertalon 66	
3	-4	050800072	5702-080	1	TIGE INF RENF/M705/LT	CW614N(CuZn39Pb3)	
4	-3	034600007	4925-460a	1	ROND/M705/LT	CW614N(CuZn39Pb3)	
5	-3	034000033		1	JT/Ø13.10*Ø1.6/83IRHD/EPDM/E P851/LJF/A-M	1	
6	-3	034400016	4925-6c	1	BG ROB/M705/POM-H/ØE=15,9	1	
7	-4	031700007	4925-14b	1	GUIDE/M705/LT	brass CW614N(CuZn39Pb3)	
8	-3	031500011	4925-150d	1	ETOUPE/M705/LT/M18x1,25EXT- M12x1,25INT	CW614N(CuZn39Pb3)	
9	-3	059120091	3-4925-912	1	ENS TIGE SUP/PAST/M706/DBLE ETOUPE	CW614N(CuZn39Pb3) + Celeron	
10	-2	037000003	4646-14c	1	PLQE C750 AC #7,05	STEEL DIN1623	
11	-2	057500123	1-4925-10g	1	VOL NOIR M705 O-C	PA6.6+30%GF black	
12	1	034600063		1	ROND C800 AC M6 De14 E1.2	STEEL	
13	1	033300057		1	ECROU M6 DIN985	STEEL	
14	1	058400180		1	CAPE/M705/NOIR/DBI 74H4	PE	BLACK -RAL 9005 -
15	-3	036100033	1-4646-55	1	FIL/C750/BR/FRITTE/ØP6,H3/20u	sinter BRONZE 20µ	
16	-2	034000108		1	JT/Ø7.1*Ø1.6/83IRHD/EPDM/EP8 51/LJF/A-M	EPDM 80SH EP851 80DIDC	
17	-3	031600016	4-4646-16a	1	SIEGE/C750/LT/M10x0,75/PR 2 FILTRES	brass CW614N(CuZn39Pb3)	
18	-2	031300011	1-5515-18a	1	PASTILLE/M705/PA/ØE5,2	1	
19	-2	034000075		1	JT/Ø3.68*Ø1.78/83IRHD/EPDM/E P851/LJF/A-M	1	
20	-3	033900008	A4.2907.2560. 3	1	PISTON/C750/Ø30,4	brass CW614N(CuZn39Pb3)	
21	-2	034000109		1	JT/Ø25.07*Ø2.62/80IRHD/EP851/ LJF/A-M	1	
22	-2	032200027	A4.2907.2565. 2	1	RESSORT/C750/INOX	INOX 1.4568K+A	Stainless Steel

M70600164

Ceodeux S.A. - Meditec

06/21/2012

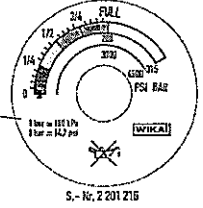
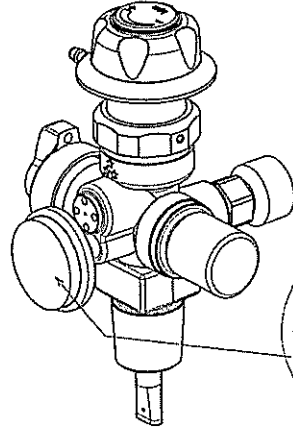
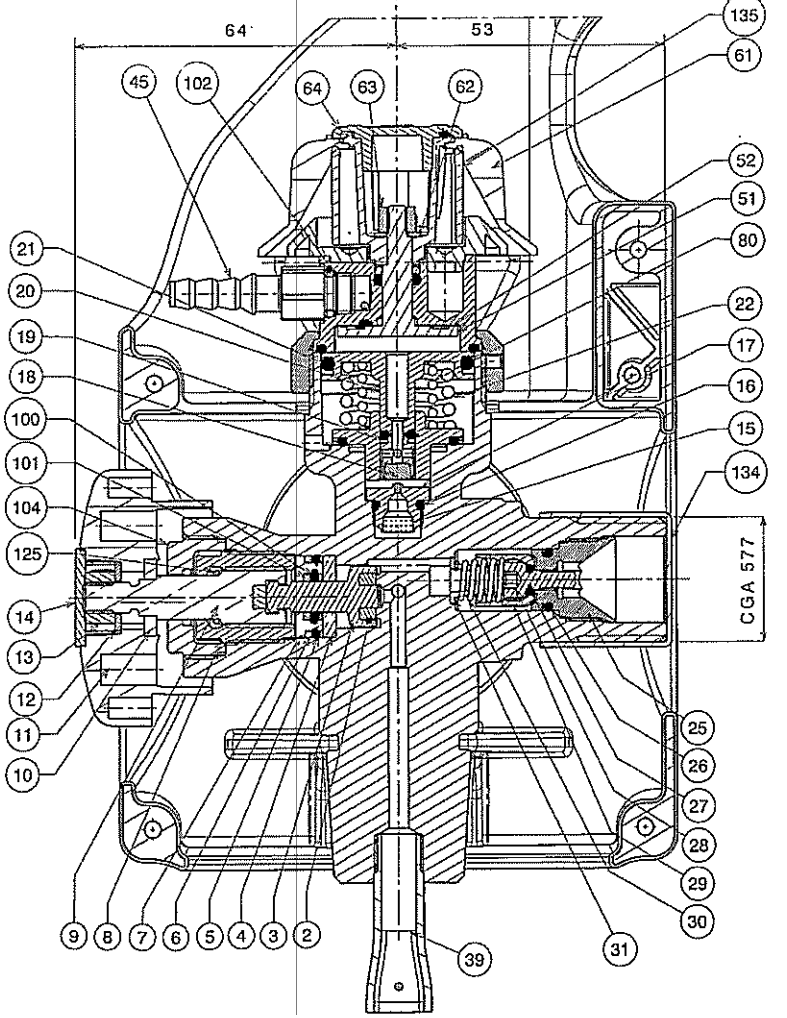
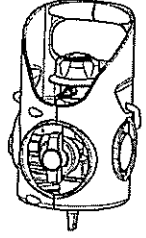
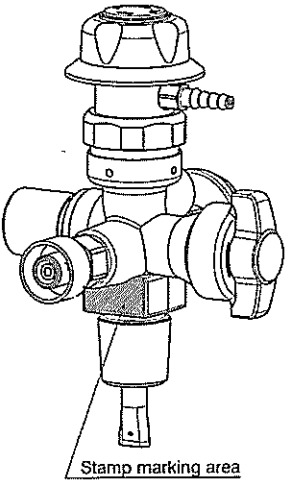
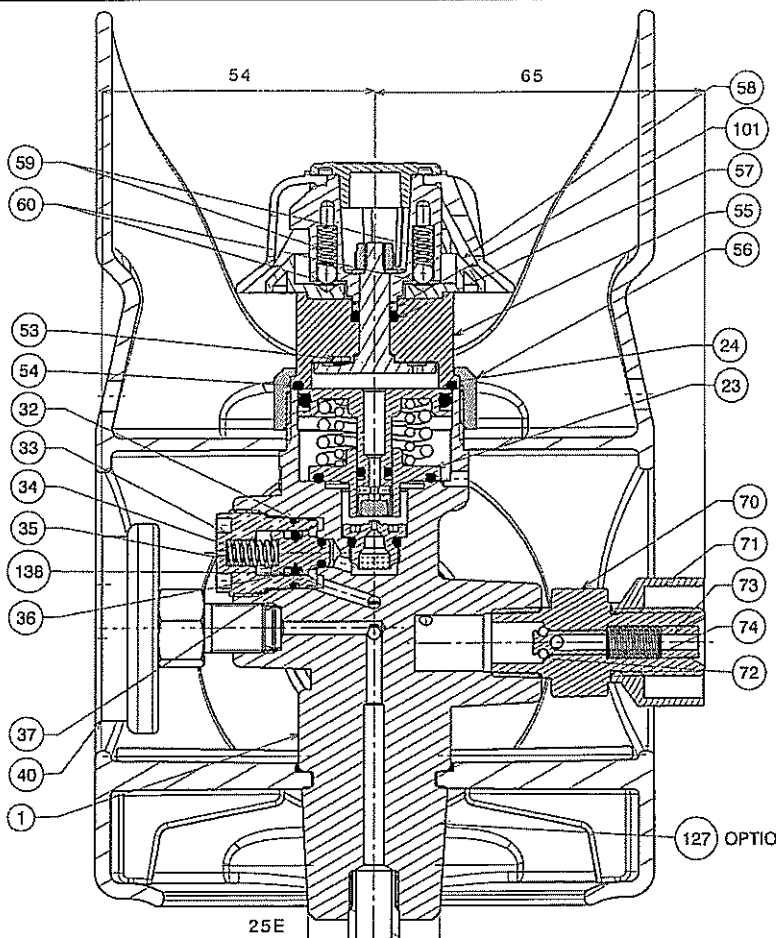
Pos.	Lev.	Article	Drawing	Qty	Description	Basic Material	Remarks
23	-3	051700013	5515-170a	1	GUIDE-PISTON/M711/LT/D13xD2 0,3	brass CW614N(CuZn39Pb3)	
24	-2	090600400900		1	JTORI/Ø20,35*Ø1,78/83IRHD/EP8 51/LJF/B	EPDM 80 IRHD	
25	-3	053260126	5-4925-326a	1	BOUCHON/M706/LT/M16x1/CGA5 77	CW614N(CuZn39Pb3)R430	
26	-2	034000106		1	JT/Ø8.73*Ø1.78/80IRHD/EPDM/E P851/LJF/A-M	1	
27	-2	034000066		1	JT/Ø2,75*Ø1,6/83IRHD/EPDM/EP 851/LJF/A-M	EPDM 80SH EP851 83IRHD	
28	-3	053000014	2-4925-300a	1	VIS CLAPET REMPL/Lg 14/CGA577	CW614N(CuZn39Pb3)	
29	-3	053300006	12-4925-330a	1	ECROU CLAPET REMPL M705	CW614N(CuZn39Pb3)	
30	-2	052200006	4925-220b	1	RESSORT CONIQUE M705 BR	BRONZE PHOSPH.	
31	-2	036100002	0339.0051.0	1	FIL/M705/BR	BRONZE 45µ	
32	-2	034000103		1	JT/Ø11,60*Ø1,20/83IRHD/EPDM/ EP851/LJF/B	EPDM 80SH EP851 80DIDC	
33	-3	053260059	7-4870-13	1	BOUCHON/M706/LT/M17x1/RPV 3-4b/NO NRV	CuZn classe1 BL2	
34	-3	052200092	9-4790-22e	1	RESSORT/RPV 3-4BAR/NO NRV/M706/Cu.Bery	Cuivre Beryllium CuBe2	Ressort RPV 3-4 bar sans NRV
35	-4	052000057	1-5515-35b	1	CLAPET/RPV/Ø8,8/NO NRV/LT/	CW614N-R500 (CuZn39Pb3)	
36	-2	054000133		1	JT/Ø5,28x1,78/80IRHD/EPDM/EP 851/LJF/A-M	EPDM 80 IRHD	
37	-3	034000066		1	JT/Ø2,75*Ø1,6/83IRHD/EPDM/EP 851/LJF/A-M	EPDM 80SH EP851 83IRHD	
39	1	052700000	5820-270e	1	TUBE/M966/LT/G1/8*ØE10/L35	CW614N or CW508L	bout aplati
40	1	058200013	6-4925-820	1	MANO/Ø40/0-315BAR/4500PSI O2 WIK A G1/8"		double échelle
45	-3	056400133	1-5515-45c	1	NIPPLE PORTE TUYAU/LT/CHR/M8x1/	LT CHR BRILLANT svt TS1	prendre le solde cordier prochaine cde
51	-3	055500010	3-4925-550a	1	AXE BAR. DEBITS INTERMEDIAIRES/	Laiton CW614N	
52	-2	058900051	6-5515-52c	1	DISQUE BAR MED 25L/P2=4,5BAR/ep0,1	Ni	0, ½, 1, 2, 3, 4, 6, 8, 10,12, 15, 25 DISC MAXIFLOW 4,5
53	-2	054000010		4	JT/Ø1,6*Ø1,6 /83IRHD/EPDM/EP851/LJF/A-M	EP851 80DIDC	
54	-2	034000107		1	JT/Ø28,3*Ø1,78/83IRHD/EPDM/E P851/LJF/A-M	EPDM 80SH EP851 80DIDC	
55	-3	050400024	1-5898-040f	1	CORPS DE BAR. DEBITS INTER RH/CHROME	Laiton CW614N/CHROME	
56	-2	053300005	15-4925-330c	1	ECROU BAR MED M706 M35x1,5	Alu EN AW-2011 (AlCu6BiPb)	ANODISATION NOIR (BLACK) CORSE E=0.009
57	-2	034000078		1	JT/Ø6,07*Ø1,78/83IRHD/EPDM/E P851/LJF/A-M	EPDM 80SH EP851 80DIDC	
58	-2	054400024	9-4925-440b	1	BAGUE DE DEBIT BAR MED 12/BAR INTER	PA6 30%GF	
59	-2	052200001	A4.2907.2643. 0	2	RESSORT BILLE BARILLET	STAINLESS STEEL AISI 301	
60	-2	055400002		2	BILLE BARILLET/PA6.6/ D3,969	KNST PA6.6 Kogel Geslepen	aussi CO2 Inc / McMaster
61	-2	057500246	1-5515-61e	1	VOL/EUR/PLASTIC BAR.3.P./0-25l/min/NOIR	PA6 + 30%GF	RAL 9005
62	-2	054600018		1	ROND/M950/LT/DIN 125-1 A M4	BRASS	
63	-2	053300008		1	ECROU INOX M4 DIN985	STAINLESS STEEL AISI 316	

Pos.	Lev.	Article	Drawing	Qty	Description	Basic Material	Remarks
64	1	058400003	5515-64f	1	CAPE PA6.6/BAR/DEBITS INTER/NOIR/	PA6 +30%GF black	Bouchon volant barillet en 2 parties
70	--4	056300231	13-5515-630	1	RAC/LT/PRISE AU/1/4"-1/4"NPT/L42	BRASS CW614N-R430 EN12164	
71	-3	051400038	5515-140	1	GUIDE/LT/PRISE AU O2/G1/4"/L18,3		
72	-2	054000009		1	JT/Ø2.4*Ø1.9 /83IRHD/EPDM/EP851/LJF/A-M	EP851 80DIDC	
73	--4	052000054	1-4925-200b	1	CLAPET/QC DISS1240/NPT/	CW614N-R430(CuZn 39Pb3)	
74	--3	052200085	3-5515-220a	1	RESSORT/DISS/INOX/Lg 26,5/DI4,9/	INOX DIN17224 N°1.4568	
80	-2	052200081	2-5515-220	1	RESSORT/M706/ØE15,6/L20/Ø1,7	INOX DIN17224 N°1.4310	Stainless Steel
100	-3	034000078		1	JT/Ø6.07*Ø1.78/83IRHD/EPDM/E P851/LJF/A-M	1	
101	-2	034400017	1-4925-6b	1	BG ROB/M705/POM-H/ØE=8,9	DELTRIN (POM-H)	
101	--3	034400017	1-4925-6b	1	BG ROB/M705/POM-H/ØE=8,9	1	
102	-2	034000078		1	JT/Ø6.07*Ø1.78/83IRHD/EPDM/E P851/LJF/A-M	EPDM 80SH EP851 80DIDC	
104	-2	051500131	1-4925-150b	1	ETOUBE/M706/LT/M24x1,25/HEX 20/SUP/	CW614N(CuZn39Pb3)	
125	-2	034600103	4646-460	1	ROND/C755-C760/PA6.6/Ø8,5/Ø1 0,3/EP.1	PA6.6	RONDELLE ANTI-BLOCAGE INDUTEC RONDELLE ANTI BLOCAGE
134	1	058400151		1	CAPE/M706/FILLING PORT/CGA577/		
135	-2	057500228	5515-62g	1	VOLANT INFERIEUR BARILLET/M706	PA6 + 30% GF	INSERT FOR FLOW KNOB HANDWHEEL
138	-3	054400025	3-5515-138	1	BG/RPV 3-4bar/NO NRV/EPDM90SH/Ø16x1,40/	EPDM 90 SHORE	

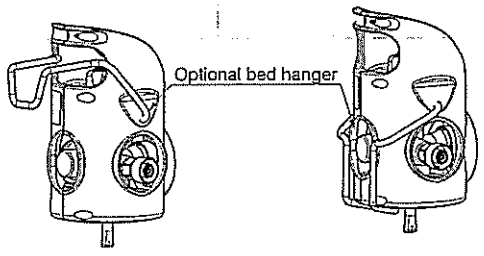
MARKING

M70600164 O2 25E CGA577 WP3000 PSI YYYY/MM
made in luxemburg

Refer to ISO 16016 for protection notice
 Dimensions in mm unless otherwise specified
 General tolerances : ISO 2768-mH
 edges of undefined shape : ISO 13715
 Indications of surface texture: ISO 1302
 tolerances of form, orientation and location : ISO 1101 & 8015
 classification of dimensions & finishings : critical ∇ main Δ



Performance data	
Gas:	O2
Inlet pressure:	P1= 3000 psi
Regulating pressure:	P2= 65 psi
Flow settings (acc. En ISO 10524-3)	0, 1/2, 1, 2, 3, 4, 6, 8, 10, 12, 15, 25



Total valve weight (including guard + bed hanger): 1,47 Kg

Ind	Mod. n°	Modification	By	Date
Material :			Designation : M706 Australia 4,5 BAR 25E CGA577 Std Handwheel	
Scale : 1/1 Date : 12/07/11 Name : SH Check by : 2/6/12		Art: M70600164 3D inspection: Drawing N° : 164-5515		

GEODEUX S.A.
MEDITEC

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