Manufacturer Evidence

Status : Versioned

Certificate change history

Date received :	21/12/2012
Certificate printed :	No

New Notification

Notification details

Evidence identifier:	DV-2012-MC-19773-1
Submission identifier:	DM-2012-07310-1
Version number:	1
Sponsor's own reference:	SMT - Medical Gas Regulators

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:	SMT SAS (France)[48665]
Manufacturer address as on certification:	5 rue de la Labergement Genlis Dijon F-21110 France S [161852]

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/FR/607-2-Rev-1
Certificate issue date: (dd/mm/yyyy)	27/01/2009
Certificate expiry date: (dd/mm/yyyy)	04/07/2013
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 - 03_FR_607_2_Rev1_9342CE_dispositifsmedicaux.p

Supporting documents:			
#	Document Type	Description	Method

Related Active ARTG Entry Information:

History

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

APRAGAZ

Member of CEOC INTERNATIONAL

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http://www.apragaz.com
info@apragaz.com

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

NOTIFIED BODY EC CERTIFICATE OF CONFORMITY In accordance with Appendix II of the Medical Devices Directive 93/42/EC		Certificate N° 03/FR/607-2-REV 1 Page 1/2
Manufacturer	Name	SMT S.A.S.
	Address	Rue de Labergement, 5 F - 21110 Genlis FRANCE
Production facilities	Name	SMT S.A.S.
	Address	Rue de Labergement, 5 F - 21110 Genlis FRANCE

Concerned Equipment: See page 2/2

Date : 27/01/2009 Name : Ch. Leplat Position General Manager

Notified body identification number : 0029

Signature

Notified body stamp : APRAGAZ Belgium Inspecting Authority

Notified body reference : 0307/P6161/ZMEDI01

APRAGAZ

Member of CEOC INTERNATIONAL

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NOTIFIED BODY EC CERTIFICATE OF CONFORMITY

In accordance with Appendix II of the Medical Devices Directive 93/42/EC

Certificate N° 03/FR/607-2-REV 1

Products concerned :

Product identification	References
Pinindex	n° 2519...
DM 200 GD	n° 2900...
DM 200 TGD	n° 2950...
CENTRALE ECOGAZ MEDICALE	n° 2993...
MODULE ECOGAZ MEDICAL	n° 2993...
DUOBLOC/CENTRALE ECOGAZ MEDICALE	n° 2993...
CENTRALE CEN 10 MEDICALE	n° 3901...
MODULE MOD 10 MEDICAL	n° 3901...
HCR 25	n° 2907...
DM 20	n° 2935...
DM 20 GD	n° 2953...
HBSI 240 – 8 FPM – NO-MEDICAL	n° 2991...

This is to certify that the Quality Management System of the above mentioned manufacturer has been assessed against the requirements of Appendix 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 04/07/2013.

Date : 27/01/2009 Name : Ch. Leplat Position **General Manager**

Notified body identification number : **0029**

Signature

Notified body stamp : APRAGAZ Belgium Inspecting Authority

Notified body reference : 0307/P6161/ZMEDI01