MAQUET

EC DECLARATION OF CONFORMITY

according to Annex II to Council Directive 93/42/EEC of June 14, 1993

Manufacturer	Maquet Critical Care AB	
Address	SE-171 95 Solna, Sweden	
Medical device	*Critical Care Ventilator*	
Product identification	VAVD Controller	965561
Accessories Covered:	Maintenance kit	510163
	Hanger for pole mounting	510162
Separately CE marked Accessories Covered:	Sterile Tubing assembly	500050
Classification	Class I (according to Annex IX to Council Directive 93/42/EEC)1	

We declare the compliance of the above medical device with the requirements of the Council Directive 93/42/EEC of June 14, 1993 and LVFS 2003:11, the Swedish implementation of the same directive, and their amendments. Any modification of the medical device not authorized by us will invalidate this declaration.

The conformity of the full quality assurance system is certified with Certificate No.41313289, dated 2004-04-28 , by the following Notified Body:

Intertek Semko AB
Box 1103
SE-164 22 Kista, Sweden

The identification number of the notified body for implementation of the procedure set out in Annex II to the above Directive is 0413.

Place and date	Solna, 2004-07-13	
Name	*Lennart Nyström* (Vice President Quality)	*Anna Keck* (Proxy Regulatory Affairs Manager *Perfusion*)
Signature		

For conditions of guarantee and liability please refer to our General Conditions of Sale.

LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

2006-08-08 Dnr 484:2006/47307 1(1)

Maquet Critical Care AB
Röntgenvägen 2
SE-171 95 SOLNA
Sweden

To whom it may concern

FREE SALES CERTIFICATE

It is hereby certified that the medical devices listed below are marketed and manufactured by Maquet Critical Care AB, Röntgenvägen 2, SE-171 95 SOLNA, Sweden.

Model	**Common name**
Servo-i	Intensive Care ventilator
Servo-s	Intensive Care ventilator
Servo Ultra Nebulizer 145	Nebulizing of Drugs
Servo Guard	Breathing filter
Bi-phasic Ventilator module	Bi-phasic ventilation
Servo Screen 390	Ventilation monitor
Gasmixer 961/962/965	Mixer for medical gases
Vaporizer 950/951/952/953	Vaporizer for anesthesia agents
Compressor Mini	Compressor for use with lungventilators
JOSTRA-HL 20	Heart-lung machine
JOSTRA-HL 20 Classic	Heart-lung machine
JOSTRA-HL 30	Heart-lung machine
JOSTRA-RotaFlow	Centrifugal pump
JOSTRA-HCU 20	Heater-cooler unit
JOSTRA-HCU 30	Heater-cooler unit
JOSTRA-VAVD Controller	Vacuum control unit
NovaCirc	Local perfusion system

They are allowed to be marketed and freely sold in Sweden and may be exported without any restrictions.

This certificate is valid until August 13, 2011

On behalf of the Medical Products Agency

Lars Johansson
Inspector

LÄKEMEDELSVERKET • MEDICAL PRODUCTS AGENCY •

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Internet: www.mpa.se E-mail: registrator@mpa.se

EC CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM APPROVAL CERTIFICATE

(Annex II of the Directive 93/42/EEC on Medical Devices)

No. 41313289

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation LVFS 2003:11 to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned legislation.

Manufacturer:

Maquet Critical Care AB
Röntgenvägen 2
SE-171 95 Solna
Sweden

Product category:

Anaesthesia, Intensive-Care-Ventilation and Perfusion systems

Date of expiry:

13 August 2011

The Certificate is valid for the devices which are stated in the present MDD – Product list archived at Intertek Semko AB

Stockholm
13 August 2006

Intertek Semko AB
Notified Body MDD

The original certificate issued on
30 October 2003

Marie Olsson
Certification Manager MDD

Intertek Semko AB is a Notified Body according to the Council Directive 93/42/EEC concerning medical devices.
Identification number 0413.

Intertek ETL SEMKO

2003-08-28

Duplicate

CERTIFICATE

No. 1419344

Maquet Critical Care AB

Solna (Sweden)

Development, manufacture and marketing of Anaesthesia, Intensive-Care-Ventilation and Perfusion systems.

The environmental management system complies with

SS-EN ISO 14001:2004

The conditions and extent of this certificate are stated in the certification decision

Kista, 18 January 2006

SEMKO-DEKRA Certification AB

The original certificate issued on 24 June 2004

CERTIFIED ISO 14001 SEMKO-DEKRA

SEMKO-DEKRA

SEMKO DEKRA-ITS CERTIFICATION SERVICES

SWEDAC ACKREDITERING 1639 EMS