

EC CERTIFICATION

FULL QUALITY ASSURANCE SYSTEM

Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the Swedish 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 directive, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Pharma Systems AB

Main Site: Rubanksgatan 9, SE-741 71 Knivsta, Sweden

Product Category:

- Breathing Systems for Anaesthesia and Intensive Care

For further identification of the products covered, see the MDD product list/product schedule.

Certificate Number:

41311728-01

Initial Certification Date:

16 June 1998

Certificate Valid from:

17 September 2018

Certificate Expiry Date:

16 September 2023



Ackred. nr 1003
ISO/IEC 17021


Peter Nermander

Certification Authority MDD
Intertek Semko AB, Kista, Sweden

14 September 2018

Signed Date

Intertek Semko AB
Box 1103, SE-164 22 Kista, Sweden
Telephone +46 8 750 00 00
medtechsweden@intertek.com

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body.

Intertek Semko AB is a Notified Body according to Directive 93/42/EEC on medical devices, with identification number 0413.



Products included in the Certificate No: 41311728-01
 Issued to: **Pharma Systems AB**
 Rubanksgatan 9
 SE-741 71 Knivsta
 Sweden

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Heat- and Moisture Exchanger with Bacterial/Viral Filter (tidal volume 50-900 ml)					
Pharma Mini Basic	6100	Ila	No	35530	*
Pharma Mini Basic	6100s	Ila	Yes	35530	*
Pharma Mini Port	6120	Ila	No	35530	*
Pharma Mini Port	6120s	Ila	Yes	35530	*
Pharma Mini Port 2	6121	Ila	No	35530	Feb 17, 2011
Pharma Mini Port 2	6121s	Ila	Yes	35530	Feb 17, 2011
Pharma Mini Port Angle	6130	Ila	No	35530	*
Pharma Mini Port Angle	6130s	Ila	Yes	35530	*
Heat- and Moisture Exchanger with Bacterial/Viral Filter (tidal volume 100-1200 ml)					
Bact HME Midi Port	6310	Ila	No	35530	*
Bact HME Midi Port	6310s	Ila	Yes	35530	*
Bact HME Midi Port Angle	6320	Ila	No	35530	*
Bact HME Midi Port Angle	6320s	Ila	Yes	35530	*
Bact Trap Midi HEPA HME Port	6340	Ila	No	35530	Jan 7, 2013
Bact Trap Midi HEPA HME Port	6340s	Ila	Yes	35530	Jan 7, 2013
Bact Trap Midi HEPA HME Port Angle	6350	Ila	No	35530	Jan 7, 2013
Bact Trap Midi HEPA HME Port Angle	6350s	Ila	Yes	35530	Jan 7, 2013
Heat- and Moisture Exchanger with Bacterial/Viral Filter (tidal volume 150-1500 ml)					
Bact HME Basic	6000	Ila	No	35530	*
Bact HME Basic	6000s	Ila	Yes	35530	*
Bact HME Port	6020	Ila	No	35530	*
Bact HME Port	6020s	Ila	Yes	35530	*
Bact Trap HEPA HME Basic	7030	Ila	No	35530	*
Bact Trap HEPA HME Basic	7030s	Ila	Yes	35530	*
Bact Trap HEPA HME Port	7040	Ila	No	35530	*
Bact Trap HEPA HME Port	7040s	Ila	Yes	35530	*

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Intertek Semko AB

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Telephone +46 8 750 00 00, Fax +46 8 750 60 30, www.sweden.intertek-etlsemko.com

Registered in Sweden: No SE556024059901, Registered office: As address

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Heat- and Moisture Exchanger (tidal volume 50-900 ml)					
HME 10 Basic	6060	Ila	No	35530	*
HME 10 Basic	6060s	Ila	Yes	35530	*
HME 10 Port Angle	6061	Ila	No	35530	*
HME 10 Port Angle	6061s	Ila	Yes	35530	*
HME 10 Port	6063	Ila	No	35530	*
HME 10 Port	6063s	Ila	Yes	35530	*
HME 10 Port 2	6065	Ila	No	35530	Feb 17, 2011
HME 10 Port 2	6065s	Ila	Yes	35530	Feb 17, 2011
Heat- and Moisture Exchanger (tidal volume 100-1200 ml)					
HME Midi 11	6305	Ila	No	35530	Dec 28, 2011
HME Midi 11 Angle	6307	Ila	No	35530	Dec 28, 2011
Heat- and Moisture Exchanger (tidal volume 150-1500 ml)					
HME 12 Basic	6070	Ila	No	35530	*
HME 12 Basic	6070s	Ila	Yes	35530	*
HME 12 Port	6072	Ila	No	35530	*
HME 12 Port	6072s	Ila	Yes	35530	*
Heat- and Moisture Exchanger for Neonatal and Infant Patients					
Pharma Neo Basic	6215	Ila	No	35530	*
Pharma Neo Basic	6215s	Ila	Yes	35530	*
Pharma Neo Port	6220	Ila	No	35530	*
Pharma Neo Port	6220s	Ila	Yes	35530	*
Heat- and Moisture Exchanger for Tracheostomized Patients					
Pharma Trach Basic	6240	Ila	No	35530	*
Pharma Trach Basic	6240s	Ila	Yes	35530	*
Pharma Trach Multi-Function	6241	Ila	No	35530	*
Pharma Trach Multi-Function	6241s	Ila	Yes	35530	*
Pharma Trach Suction	6242	Ila	No	35530	*
Pharma Trach Suction	6242s	Ila	Yes	35530	*
Pharma Trach Basic Oxygen Port	6243	Ila	No	35530	*
Pharma Trach Basic Oxygen Port	6243s	Ila	Yes	35530	*
Pharma Trach Basic MultiPac	6245	Ila	No	35530	*
Pharma Trach Basic MultiPac	6245s	Ila	Yes	35530	*
Pharma Trach Multi-Function Pac	6246	Ila	No	35530	*
Pharma Trach Multi-Function Pac	6246s	Ila	Yes	35530	*
Pharma Trach FilterPac	6250	Ila	No	35530	*
Pharma Trach FilterPac	6250s	Ila	Yes	35530	*
Pharma Trach FilterPac Oxygen Port	6251	Ila	No	35530	*
Pharma Trach FilterPac Oxygen Port	6251s	Ila	Yes	35530	*
Pharma Trach Cassette Hook	6255	Ila	No	35530	*
Pharma Trach Cassette Hook	6255s	Ila	Yes	35530	*

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Registered in Sweden: No SE556024059901, Registered office: As address

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Oxygen Supply Gripper	6258	Ila	No	35530	*
Oxygen Supply Gripper	6258s	Ila	Yes	35530	*
Oxygen Supply Gripper-Tube	6260	Ila	No	35530	*
Oxygen Supply Gripper-Tube	6260s	Ila	Yes	35530	*
Oxygen Supply Tube	6261	Ila	No	35530	*
Oxygen Supply Tube	6261s	Ila	Yes	35530	*

**Bacterial/Viral Filter
(tidal volume 50-900 ml)**

Bact Trap Mini Basic	7050	Ila	No	35070	*
Bact Trap Mini Basic	7050s	Ila	Yes	35070	*
Bact Trap Mini Port 2	7054	Ila	No	35070	Feb 17, 2011
Bact Trap Mini Port 2	7054s	Ila	Yes	35070	Feb 17, 2011
Bact Trap Mini Port	7055	Ila	No	35070	*
Bact Trap Mini Port	7055s	Ila	Yes	35070	*
Bact Trap Mini Port Angle	7061	Ila	No	35070	*
Bact Trap Mini Port Angle	7061s	Ila	Yes	35070	*

**Bacterial/Viral Filter
(tidal volume 100-1200 ml)**

Bact Trap Midi Port	7110	Ila	No	35070	*
Bact Trap Midi Port	7110s	Ila	Yes	35070	*
Bact Trap Midi Port Angle	7120	Ila	No	35070	*
Bact Trap Midi Port Angle	7120s	Ila	Yes	35070	*
Bact Trap Midi HEPA Port	7140	Ila	No	35070	*
Bact Trap Midi HEPA Port	7140s	Ila	Yes	35070	*
Bact Trap Midi HEPA Port Angle	7150	Ila	No	35070	*
Bact Trap Midi HEPA Port Angle	7150s	Ila	Yes	35070	*

**Bacterial/Viral Filter
(tidal volume 150-1500 ml)**

Bact Trap Basic	7010	Ila	No	35070	*
Bact Trap Basic	7010s	Ila	Yes	35070	*
Bact Trap Port	7011	Ila	No	35070	*
Bact Trap Port	7011s	Ila	Yes	35070	*
Bact Trap Gas Return System	7015	Ila	No	35070	*
Bact Trap Gas Return System	7015s	Ila	Yes	35070	*
Bact Trap HEPA Basic	7070	Ila	No	35070	*
Bact Trap HEPA Basic	7070s	Ila	Yes	35070	*
Bact Trap HEPA Port	7080	Ila	No	35070	*
Bact Trap HEPA Port	7080s	Ila	Yes	35070	*

**Flexible link between patient and
breathing system**

Elbow	4610	Ila	No	34838	*
Elbow	4610s	Ila	Yes	34838	*
Elbow Economy	4611	Ila	No	34838	*
Elbow Economy	4611s	Ila	Yes	34838	*

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Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Swivel Elbow	4615	Ila	No	34838	*
Swivel Elbow	4615s	Ila	Yes	34838	*
Swivel Port	4616	Ila	No	34838	*
Swivel Port	4616s	Ila	Yes	34838	*
PharmaFlex M-Flex 15/22	5001	Ila	No	34838	*
PharmaFlex M-Flex 15/22	5001s	Ila	Yes	34838	*
PharmaFlex Direct Swivel Elbow	5002	Ila	No	34838	*
PharmaFlex Direct Swivel Elbow	5002s	Ila	Yes	34838	*
PharmaFlex Direct Swivel Port	5003	Ila	No	34838	*
PharmaFlex Direct Swivel Port	5003s	Ila	Yes	34838	*
PharmaFlex Direct Swivel Port 22mm Female	5004	Ila	No	34838	*
PharmaFlex Direct Swivel Port 22mm Female	5004s	Ila	Yes	34838	*
PharmaFlex Swivel Elbow	5005	Ila	No	34838	*
PharmaFlex Swivel Elbow	5005s	Ila	Yes	34838	*
PharmaFlex Swivel Port	5006	Ila	No	34838	*
PharmaFlex Swivel Port	5006s	Ila	Yes	34838	*
PharmaFlex Swivel Port 22mm Female	5007	Ila	No	34838	*
PharmaFlex Swivel Port 22mm Female	5007s	Ila	Yes	34838	*
PharmaFlex Straight 15mm Female	5009	Ila	No	34838	*
PharmaFlex Straight 15mm Female	5009s	Ila	Yes	34838	*
PharmaFlex Straight	5010	Ila	No	34838	*
PharmaFlex Straight	5010s	Ila	Yes	34838	*
PharmaFlex Straight 22/22	5010S	Ila	No	34838	March 15, 2011
PharmaFlex Straight 22/22	5010Ss	Ila	Yes	34838	March 15, 2011
PharmaFlex Direct Straight	5011	Ila	No	34838	*
PharmaFlex Direct Straight	5011s	Ila	Yes	34838	*
PharmaFlex Direct Straight Female	5012	Ila	No	34838	*
PharmaFlex Direct Straight Female	5012s	Ila	Yes	34838	*
PharmaFlex Direct Elbow	5013	Ila	No	34838	*
PharmaFlex Direct Elbow	5013s	Ila	Yes	34838	*
PharmaFlex Elbow	5015	Ila	No	34838	*
PharmaFlex Elbow	5015s	Ila	Yes	34838	*

* Product added before December 3, 2008.

Date of Issue: 14 September 2018

Intertek Semko AB
Notified Body MDD

A blue ink signature of Peter Nermander.

Peter Nermander
Certification Authority MDD

This product list is only valid together with the referenced, valid EC certificate.

The GMDN codes are assigned by the manufacturer and are only provided for convenience.

Intertek Semko AB is a Notified Body according to the Directive 93/42/EEC on medical devices, with identification number 0413.

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Registered in Sweden: No SE556024059901, Registered office: As address

Certificate No: 41311728-01
Date: 14 September 2018
Handled by: Lisa Gray
E-mail: medtechsweden@intertek.com

Pharma Systems AB
Rubanksgatan 9
Knivsta
SE-741 71
Sweden

Purpose	Assessment according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II.
Activity	Recert audit was performed 06/08-Dec-17 & 12/14-Dec-17 in Knivsta by Goran Nerby. The technical file was reviewed by Negar Klingenstierna at Intertek's office.
Scope of assessment	Breathing Systems for Anaesthesia and Intensive Care, Class IIa
Result	All non conformities raised in the activities have been closed.
Certificate Valid from	17 September 2018
Conclusions/Decisions	Referring to the above a Certificate of Conformance with the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II will be issued. The Certificate is valid for products specified in the "MDD – Product List".
Follow-up assessments	Follow-up assessments are going to be performed once a year.
Appeals	Any appeal against this decision will be processed by an appeals panel as Intertek. The appeal shall be submitted to Intertek Semko AB, PO-Box 1103, SE-164 22 Kista, Sweden.
Others	Any complaints, from customers and others, and corrective actions concerning your certified quality system shall be documented and retained. Upon request Intertek Semko has the right to review this documentation.

Intertek Semko AB
Notified Body MDD


Peter Nermander
Certification Authority MDD

DECLARATION OF CONFORMITY

We, the undersigned, hereby declare that devices, specified below, conform to the Medical Device Directive 93/42/EEC (Swedish Implementation LVFS 2003:11)

Manufacturer's name Pharma Systems AB

Manufacturer's address Rubanksgatan 9
741 71 Knivsta, Sweden

Type of devices Breathing devices

Products	Type
Bact HME	6000, 6020
Bact HME Midi	6310, 6320
Bact Trap Midi HEPA HME	6340, 6350
HME 10	6060, 6061, 6063, 6065
HME Midi11	6305, 6307
HME 12	6070, 6072
Pharma Mini	6100, 6120, 6121, 6130
Pharma Neo	6215, 6220
Pharma Trach	6240, 6241, 6242, 6243, 6245, 6246, 6250, 6251, 6255, 6258, 6260, 6261
Bact Trap	7010, 7011
Bact Trap Midi	7110, 7120
Bact Trap Gas Return	7015
Bact Trap HEPA HME	7030, 7040
Bact Trap Mini	7050, 7054, 7055, 7061
Bact Trap HEPA	7070, 7080
Bact Trap Midi HEPA	7140, 7150

Product classification IIa

Classification rule 3

Listed products are non-invasive devices for use in breathing systems in anaesthesia and intensive care to treat breathing gases.

Notified Body 0413, Certificate number 41311728-01

Knivsta, Sweden, 2018-12-01

Pharma Systems AB



Raul Marmor
Quality Manager



Pharma Mini

Heat and moisture exchanger combined with bacterial/viral filter for smaller tidal volumes

Product specification

Tidal volume (ml)	50-900
Dead space (ml) Basic	26
Straight/angled w. port	23
Weight (g)	15

Resistance cm H₂O

Basic	20 LPM	1,4
Port	20 LPM	1,5
Port Angle	20 LPM	1,4

Filtration efficiency

Bacterial	>99,99%
Viral	>99,99%

Moisture return

At VT 250 ml (mg H ₂ O/l air)	31,8
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Fittings: 15 Male/15 female – 22 male (mm)



Basic

Code: 6100

Box/Case: 50/500



Port

Code: 6120

Box/Case: 50/500



Port 2

Code: 6121

Box/Case: 50/500



Port angle

Code: 6130

Box/Case: 50/500

Bact-HME Midi

Medium size heat and moisture exchanger combined with bacterial/viral filter

Product specification

Tidal volume (ml)	100-1200
Dead space (ml) straight	47
Dead space (ml) angled	49
Weight (g)	29

Resistance cm H₂O

Port	30 LPM	1,4
Port Angle	30 LPM	1,3

Filtration efficiency

Bacterial	>99,99%
Viral	>99,99%

Moisture return

At VT 500 ml (mg H ₂ O/l air)	32 mg
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Fittings: 22 female/15 female – 22 male

Fittings port: 15 male – 22 female/15 female – 22 male (mm)



Port

Code: 6310

Box/Case: 50/400



Port Angle

Code: 6320

Box/Case: 50/400

COMBINED HEAT AND MOISTURE EXCHANGER WITH BACTERIAL/VIRAL FILTER

Our combined heat and moisture exchangers with bacterial/viral filters offer the user a high efficiency solution for breathing systems in a clear housing for easy inspection of secretions.

- Conical fittings in accordance with ISO standard ensure safe connection security.
- Efficient humidification prevents moisture from collecting in the tubing.
- Two HME elements to reduce risk for hypothermia.
- Efficient filters reduce potential colonization into the circuit and equipment.
- Reduces the risk of cross-infection among patients and hospital staff.
- Eliminates the need for heated wire circuits, water traps and their maintenance.
- Dry and filtered gas prevent sampling tube and analyzers from moisture and colonization.
- Initial set-up is simple, quick and secure.
- Different options ensure the right choice of device.
- Should be changed every 24 hours or more frequently if resistance increases.



Bact-Trap™ Hepa HME

- A breathing HME filter which is a combination of pleated mechanical filter and electrostatic charge attraction with high efficiency heat and moisture output.
- Designed for optimal patient comfort – smooth and round shape to prevent pressure sores on patient.
- Complies with the highest global filtration standard - ISO 23328.
- >99.9999% effective bacterial/viral filter to prevent the spread of infectious particles into the circuits, machines and manual resuscitators.
- Provides heat & moisture and isolates patients from potential bacterial/viral contamination.

Bact-HME, Bact-HME Midi and Pharma Mini

- A >99.99% effective bacterial/viral filter to prevent the spread of infectious particles into the circuits, machines and manual resuscitators.

Attention! Bact-Trap Hepa HME should not be used in combination with nebulizer, aerosol therapy or active humidification.