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:

Parker Hannifin Corp.

Precision Fluidics Division

Main Site: 245 Township Line Road, Hatfield, Pennsylvania 19440, United States

Product Category:

- Nitrous Oxide Conscious Sedation delivery and scavenging systems

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

*Previously certified by Intertek AMTAC (NB0473) to date 7 February 2018

Certificate Number:
41371964-02

Initial Certification Date:
07 February 2018*

Certificate Valid from:
19 April 2020

Certificate Expiry Date:
26 May 2024

SWEDAC ACKREDITERING
Accred. no. 1003
Certification of Management Systems
ISO/IEC 17021-1

Bob Andersson
Certification Authority MDD
Intertek Semko AB, Kista, Sweden

06 April 2020
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.

MDD – Product List

Products included in the certificate no: 41371964-02
Issued to: **Parker Hannifin Corp. – Precision Fluidics Division**
245 Township Line Road
Hatfield, Pennsylvania 19440
United States

	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Nitrous Oxide Conscious Sedation delivery and scavenging systems					
Mechanical Sedation Meters					
	MXR, White Markings for O2, 70% Max N2O C3000	IIb	No		Feb 7, 2018
	MXR, White Markings for O2, 70% Max N2O C3050	IIb	No		Feb 7, 2018
	MXR, Danish Connectors, White Body, DTL-146W	IIb	No		Feb 7, 2018
	MXR, Swedish Connectors, White Body, DTL-164W	IIb	No		Feb 7, 2018
	MDM Assembly, Std 94500011	IIb	No		Feb 7, 2018
	MDM Assembly, Canada, 91500167	IIb	No		Feb 7, 2018
	MDM Assembly, France, 50% Min O2 91500333	IIb	No		Feb 7, 2018
	MDM Assembly, Swedish, 40% Min 91500401	IIb	No		Feb 7, 2018
	MDM Assembly, Std ISO, 94500150	IIb	No		Feb 7, 2018
	MDM Assembly, UK 94500163	IIb	No		Feb 7, 2018
	MDM Assembly, Spain, 94500150SPAIN	IIb	No		Feb 7, 2018
	MDM Assembly, Australia, 30% 94500323	IIb	No		Feb 7, 2018

Intertek Semko AB
Torshamnsgatan 43, Box 1103, SE-164 22 Kista, Sweden
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

	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Digital MDM Sedation Flowmeters					
	DMDM Assy, Spain 40151602SPAIN	IIb	No		Feb 7, 2018
	40151602 Digital MDM, 30% Std ISO 91525176	IIb	No		Feb 7, 2018
	40151602 Digital MDM, 30%, Germany, Straight Fittings 91525178	IIb	No		Feb 7, 2018
	40151602 Digital MDM, 30%, Spain 91525179	IIb	No		Feb 7, 2018
	40151614 Digital MDM, 40% Sweden 91525180	IIb	No		Feb 7, 2018
	40151602 Digital MDM, 30% Israel 91525182	IIb	No		Feb 7, 2018
	40151615 Digital MDM, 30% Australia/ N.Z. 91525184	IIb	No		Feb 7, 2018
	40151616 Digital MDM, 50%, Dutch 91525185	IIb	No		Feb 7, 2018
	40151617 Digital MDM, 30%, Canada 91525186	IIb	No		Feb 7, 2018
	40151604 Digital MDM, 30%, Germany, Elbow Fittings 91525187	IIb	No		Feb 7, 2018
	40151618 Digital MDM, 30% Italy 91525262	IIb	No		Feb 7, 2018
	40151602 Digital MDM, 30% Middle East, 91525265	IIb	No		Feb 7, 2018
Gas Scavenging Apparatus / Automatic Vacuum Switch (AVS)					
	AVS with adapter hoses and Vacuum Tube Holder, AVS-5000	IIb	No		Feb 7, 2018
	AVS with Quick Disconnect, AVS-5000QD	IIb	No		Feb 7, 2018
	AUTO VAC SWITCH SYS SWIVEL MNT, AVS-5000S	IIb	No		Feb 7, 2018

Intertek Semko AB
Torshamnsgatan 43, Box 1103, SE-164 22 Kista, Sweden
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

MDD – Product List

	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Accessories - Gas Scavenging Apparatus					
	Silhouette SIL-ADPT-KIT	IIa	No		Feb 7, 2018
	Silhouette SIL-CONN-KIT	IIa	No		Feb 7, 2018
	Silhouette SILHOUETTELG	IIa	No		Feb 7, 2018
	Silhouette SILHOUETTEMD	IIa	No		Feb 7, 2018
	Silhouette SILHOUETTEPD	IIa	No		Feb 7, 2018
	Silhouette SILHOUETTESM	IIa	No		Feb 7, 2018
	Silhouette SIL-LG-12 SIL-LG-24	IIa	No		Feb 7, 2018
	Silhouette SIL-MED-12 SIL-MED-24	IIa	No		Feb 7, 2018
	Silhouette SIL-PEDO-12 SIL-PEDO-24	IIa	No		Feb 7, 2018
	Silhouette SIL-SIZER-4	IIa	No		Feb 7, 2018
	Silhouette SIL-SM-12 SIL-SM-24	IIa	No		Feb 7, 2018
	Silhouette SIL-START-PK	IIa	No		Feb 7, 2018
	Silhouette SIL-VAR-4X3	IIa	No		Feb 7, 2018

Sign Date: 06 April 2020
Valid Date: 19 April 2020

Intertek Semko AB
Notified Body MDD

Bob Andersson
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.

Intertek Semko AB
Torshamnsgatan 43, Box 1103, SE-164 22 Kista, Sweden
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

MDD – Decision Report

Certificate No: 41371964-02
Date: 06 April 2020
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

Parker Hannifin Corp. –
Precision Fluidics Division
Attn: Michael Doherty
245 Township Line Road
Hatfield, Pennsylvania 19440
United States

Purpose	Assessment to issue a new certificate due to five year extension according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II.
Activity	Certification audit was performed 16 April 2019 in Hatfield by Orpha James, and Mesfin Kassa. The technical file was reviewed by Iffat Noor 30 March 2020 at Intertek's office.
Scope of assessment	Nitrous Oxide Conscious Sedation delivery and scavenging systems, Class IIa and Class IIb
Result	1 minor non conformities were noted during the audit. Presented corrective action plans have been examined and approved by us.
Certificate Valid from	19 April 2020
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

Bob Andersson
Certification Authority MDD