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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:

Precision Optics Corporation Inc.

Main Site: 22 East Broadway, Gardner, Massachusetts, 01440, United States

Product Category:

- Endoscopes

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

* Previously certified by Intertek AMTAC (NB0473) to date 26 June 2018

Certificate Number:
41377132-00

Initial Certification Date:
14 January 2015*

Certificate Valid from:
26 June 2018

Certificate Expiry Date:
13 January 2020

SWEDAC ACKREDITERING
Ackred. nr 1003
ISO/IEC 17021

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

26 June 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.

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MDD – Decision Report

Certificate No: 41377132-00
Date: June 26, 2018
Handled by: Lena Henning
E-mail: medtechsweden@intertek.com

Precision Optics Corporation Inc.
Att: Terri Moore
22 East Broadway, Gardner
Massachusetts, 01440
United States

Purpose	Transfer of certificate 1245 CE from Notified Body AMTAC Certification Services Ltd (0473) to Notified Body Intertek Semko AB (0413) according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II.
Scope of assessment	Endoscopes, Class IIa
Issue date of certificate	26 June 2018
Conclusions/Decisions	As the result of a review, transfer of certificate 1245 CE has been accepted. Finished/released products in stock (only) with obsolete labelling may be distributed for a maximum period of six months. Referring to the above, a solitary 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

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MDD – Product Decision

Certificate No: 41377132-00
Date: August 06, 2018
Handled by: Beverley Oakley
E-mail: medtechsweden@intertek.com

Precision Optics Corporation Inc.
Att: Terri Moore
22 East Broadway, Gardner
Massachusetts, 01440
United States

Purpose

Assessment of the application dated June 21, 2018 to add new products to be included in your certified quality system according to LVFS 2003:11, Annex II (Swedish implementation of MDD 93/42/EEC).

Products concerned

Product category	Type/Model designation	Class	Sterile/ Measuring	GMDN code (not mandatory)
Endoscope	0° Stereo Endoscope	IIa	No	-
	30° Stereo Endoscope	IIa	No	-

Conclusions/Decisions

The products are similar to previously accepted products. The application has been accepted and the products can be added. Application of the CE-mark is permitted when the company's own procedures for CE-marking are fulfilled.

Follow-up assessments

At the next audit your auditor may follow-up on the implementation of the new products in the Quality system.

Appeals

Any appeal against this decision will be processed by an appeals panel at Intertek. The appeal shall be submitted to Intertek Semko AB, PO-Box 1103, SE-164 22 Kista, Sweden.

Intertek Semko AB
Notified Body MDD

Peter Nermander
Certification Authority MDD

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DD – Product List

Products included in the certificate no: 41377132-00
Issued to: **Precision Optics Corporation Inc.**
22 East Broadway, Gardner,
Massachusetts, 01440,
United States

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Endoscopes					
	0° 10mm Autoclave Laparoscope 6711-801	IIa	No	-	26 June 2018
	0° 5mm Laparoscope 6751-801	IIa	No	-	26 June 2018
	30° 10mm Laparoscope 6713-801	IIa	No	-	26 June 2018
	0° 10mm Bariatric 6761-803	IIa	No	-	26 June 2018
	30° 10mm Bariatric 6763-804	IIa	No	-	26 June 2018
	0° 5mm Laparoscope 5281-800	IIa	No	-	26 June 2018
	18° 5mm Endoscope 8332-800	IIa	No	-	26 June 2018
	30° 4mm Arthroscope 5250-817	IIa	No	-	26 June 2018
	0° 4mm Arthroscope 5250-818	IIa	No	-	26 June 2018
	30° 5mm Autoclave Laparoscope 6753-801	IIa	No	-	26 June 2018
	0° Stereo Endoscope	IIa	No	-	6 August 2018
	30° Stereo Endoscope	IIa	No	-	6 August 2018

Date of Issue: 06 August 2018

Intertek Semko AB
Notified Body MDD

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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