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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:
41377132-01

Initial Certification Date:
14 January 2015*

Certificate Valid from:
14 January 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

19 December 2019
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 – Product List

Products included in the certificate no: 41377132-01
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

Sign Date: 19 December 2019
Valid Date: 14 January 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.

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

MDD – Decision Report

Certificate No: 41377132-01
Date: 19 December 2019
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

Precision Optics Corporation Inc.
Attn: Terri Moore
22 East Broadway, Gardner,
Massachusetts, 01440,
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 12 February 2019 in Gardner by Orpha James. The technical file was reviewed by Howard Dobb at Intertek's office.
Scope of assessment	Endoscopes, Class IIa
Result	2 minor non conformities were noted during the audit. Presented corrective action plans have been examined and approved by us.
Certificate Valid from	14 January 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