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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:

Parmax AB

Main Site: Finspångsgatan 42 SE-163 53 Spånga, Sweden

Product Category:

- Dental Posts (OBL)
- Dental Reamers (OBL)

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

Certificate Number:
41319273-01

Initial Certification Date:
March 11, 2013

Certificate Valid from:
March 11, 2018

Certificate Expiry Date:
March 10, 2023

SWEDAC ACKREDITERING
Ackred. nr 1003
ISO/IEC 17021

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

February 13, 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 – Product List

Products included in the Certificate No: 41319273-01
Issued to: **Parmax AB**
Finspångsgatan 42
SE-163 53 Spånga
Sweden

Product category	Type/Model designation	Class	Sterile / Measuring	GMDN code (not mandatory)	Date added
Dental posts	Parmax Classic (see below) **Length (x):** S=Short, 7.8 mm, M=Medium, 9.3 mm L=Long, 11.8 mm EL=Extra Long, 14.2 mm SL=Super Long, 17 mm. **Diameter (y):** 1 – 6 (only 3-6 EL and SL): 1=1.05 mm 2=1.20 mm 3=1.35 mm 4=1.50 mm 5=1.65 mm 6=1.80 mm				
	Parmax Classic Titanium (PT-) Kits : PT-60 (60 pieces assorted kit) PT-120 (120 pieces assorted kit) Refills, 12 posts: PT-xy (Sizes as above)	IIa	--	38609	
	Parmax Classic Gold Plated (PG-) Kits : PG-60 (60 pieces assorted kit) PG-120 (120 pieces assorted kit) PG-240 (240 pieces assorted kit) Refills, 12 posts: PG-xy (Sizes as above)	IIa	--	38609	

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

	Paralight Fiber Glass (PL-) 15 posts Large (PL-L15) Medium (PL-M15) Small (PL-S15) Extra-small (PL-XS15) 2Extra-small (PL-XXS15) 3Extra-small (PL-XXXS15)	IIa	--	38609	
Dental Reamers	**Parmax Reamers** (PRx-y) **Length (x):** A = 28 mm (short) B = 33 mm (long) **Diameter (y):** 1=1.05 mm 2=1.20 mm 3=1.35 mm 4=1.50 mm 5=1.65 mm 6=1.80 mm **Parmax Paralight Reamers** (PLR-z) **Size (z):** 3= #3 x-small, short (28 mm) 4= #4 small, long (33 mm) 5= #5 medium, long (33 mm) 6= #6 large, long (33mm)				
	Kits: PRA-1/6 - Assorted short reamers size 1-6 PRB-1/6 - Assorted long reamers size 1-6	IIa	--	16669	
	PLR-4/6 - Assorted long Paralight reamers size 4-6	IIa	--	16669	Nov 10, 2015
	Refills, 3 pack reamers: PRA-y, PRB-y				
	Refills, 2 pack reamers: PLR-z (Sizes as above)	IIa	--	16669	Nov 10, 2015

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Signed Date: February 13, 2017
Valid Date: March 11, 2018

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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MDD – Decision Report

Certificate No: 41319273-01
Date: February 13, 2018
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

Parmax AB
Attn: Tomas Skeppmark
Finspångsgatan 42
SE-163 53 Spånga
Sweden

Purpose	Five year extension assessment according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex II
Activity	Certification audit was performed December 15, 2017 in Spånga by Gabriel Johansson. The technical file was reviewed by Maria Eklycke at Intertek's office.
Scope of assessment	- Dental Posts (OBL) - Dental Reamers (OBL) Class IIa
Result	4 minor non conformities were noted during the audit. Presented corrective action plans have been examined and approved by us.
Certificate Valid from	March 11, 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

Bob Andersson
Certification Authority MDD