

EC CERTIFICATION

PRODUCTION QUALITY ASSURANCE

Directive 93/42/EEC on Medical Devices, Annex V

We hereby declare that an examination of the under mentioned production 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 V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation, and the result entitles the organization to use the CE 0413 marking on those products listed below.

Organization:

Medental International

Main Site: José María Bustillos No. 28 Bis, 1er y 2do piso. Colonia Algarín, Delegación Cuauhtémoc, CP. 06880. Ciudad de México, México.

Product Category:

- Dental materials

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

*Previously certified by Intertek AMTAC (NB0473) to date 29 June 2018

Certificate Number:

41377502-01

Initial Certification Date:

19 May 2010*

Certificate Valid from:

19 May 2020

Certificate Expiry Date:

26 May 2024



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

Bob Andersson

Certification Authority MDD
Intertek Semko AB, Kista, Sweden

8 May 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.



Products included in the certificate no: 41377502-01

Issued to:

Medental International

José María Bustillos No. 28 Bis, 1er y 2do
piso. Colonia Algarín,
Delegación Cuauhtémoc, CP. 06880.
Ciudad de México, México.

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
Dental materials					
	ZINC PHOSPHATE CEMENT 32g + 15ml OPT451	Ila	No	-	29 June 2018
	ZINC PHOSPHATE CEMENT 50g + 25ml OPT1018	Ila	No	-	29 June 2018
	ZINC PHOSPHATE CEMENT 80g + 55ml OPT819	Ila	No	-	29 June 2018
	GLASS IONOMER TYPE I LUTING 20g + 15ml OPT391	Ila	No	-	29 June 2018
	GLASS IONOMER TYPE I LUTING 35g + 20ml OPT717	Ila	No	-	29 June 2018
	GLASS IONOMER TYPE I ORTHODONTIC 20g + 15ml OPT814	Ila	No	-	29 June 2018
	GLASS IONOMER TYPE II LINER 20g + 15ml OPT506	Ila	No	-	29 June 2018
	GLASS IONOMER TYPE II RESTORATIVE COLOR:21 (POWDER 20g + LIQUID 15ml + VARNISH 10ml) OPT392	Ila	No	-	29 June 2018
	GLASS IONOMER TYPE II RESTORATIVE COLOR:22 (POWDER 20g + LIQUID 15ml + VARNISH 10ml) OPT393	Ila	No	-	29 June 2018

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Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	GLASS IONOMER TYPE II A.R.T. 20g + 15ml + 10ml (A2) OPT510	Ila	No	-	29 June 2018
	GLASS IONOMER TYPE II A.R.T. 20g + 15ml + 10ml (A3) OPT746	Ila	No	-	29 June 2018
	Z.O.E. CEMENT TYPE I 40g + 20ml OPT599	Ila	No	-	29 June 2018
	Z.O.E. CEMENT TYPE I POWDER 75g OPT976	Ila	No	-	29 June 2018
	Z.O.E. CEMENT TYPE I POWDER 120g OPT1144	Ila	No	-	29 June 2018
	Z.O.E. CEMENT TYPE I LIQUID 30ml OPT220	Ila	No	-	29 June 2018
	Z.O.E. CEMENT TYPE I LIQUID 100 ml OPT1143	Ila	No	-	29 June 2018
	Z.O.E. CEMENT TYPE III 38g + 14ml OPT667	Ila	No	-	29 June 2018
	MULTI-PURPOSE Z.O.E CEMENT 75g + 30ml OPT825	Ila	No	-	29 June 2018
	MULTI-PURPOSE Z.O.E. CEMENT 90g + 30ml OPT882	Ila	No	-	29 June 2018
	CEMENT FOR DRESSING POWDER + LIQUID CDK	Ila	No	-	29 June 2018
	TEMPORARY CEMENT POWDER + LIQUID TC	Ila	No	-	29 June 2018
	ROOT CANAL SEALER 20g + 10ml OPT532	Ila	No	-	29 June 2018
	P.C.A. CEMENT KIT 25g + 15ml OPT452	Ila	No	-	29 June 2018
	P.C.A. CEMENT KIT 28g + 15ml OPT225	Ila	No	-	29 June 2018

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	P.C.A. CEMENT KIT 50g + 25ml OPT1021	Ila	No	-	29 June 2018
	P.C.A. CEMENT KIT 60g + 40ml OPT426	Ila	No	-	29 June 2018
	P.C.A. CEMENT KIT 80g + 40ml OPT826	Ila	No	-	29 June 2018
	DUAL CURE COMPOSITE DOUBLE SY 2g+2g OPT1146	Ila	No	-	29 June 2018
	DUAL CURE COMPOSITE DOUBLE SY 3g+3g OPT1032	Ila	No	-	29 June 2018
	DUAL CURE COMPOSITE 2g BASE + 2g CATALYST OPT1182	Ila	No	-	29 June 2018
	DUAL CURE COMPOSITE KIT 4x2g OPT670	Ila	No	-	29 June 2018
	SELF CURE COMPOSITE 3g + 3g W/BOND OPT431	Ila	No	-	29 June 2018
	SELF CURE COMPOSITE 3g + 3g W.O./BOND OPT432	Ila	No	-	29 June 2018
	SELF CURE COMPOSITE 5g + 5g W/BOND OPT622	Ila	No	-	29 June 2018
	SELF CURE COMPOSITE 7g + 7g W.O./BOND OPT647	Ila	No	-	29 June 2018
	SELF CURE COMPOSITE 7g + 7g W/BOND OPT738	Ila	No	-	29 June 2018
	SELF CURE COMPOSITE 14g + 14g W.O./BOND OPT770	Ila	No	-	29 June 2018

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	SELF CURE COMPOSITE 28g + 3ml + 3ml + 9g ETCH OPT1235	Ila	No	-	29 June 2018
	EBS BONDING LIGHT CURE 3g OPT087	Ila	No	-	29 June 2018
	EBS BONDING LIGHT CURE 5ml OPT651	Ila	No	-	29 June 2018
	DENTIN/ENAMEL BONDING 3ml OPT163	Ila	No	-	29 June 2018
	DENTIN/ENAMEL BONDING 2x3ml OPT589	Ila	No	-	29 June 2018
	DENTIN/ENAMEL BONDING 5ml OPT558	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE 20x0.28g TIPS A1 OPT1278	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE 20x0.28g TIPS A2 OPT1280	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE 20x0.28g TIPS A3 OPT1282	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE 20x0.28g TIPS A3.5 OPT1284	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE 20x0.28g TIPS A4 OPT1286	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE 20x0.28g TIPS B2 OPT1288	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE 20x0.28g TIPS B3 OPT1290	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE 20x0.28g TIPS C2 OPT1292	Ila	No	-	29 June 2018

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	MICRO HYBRID LIGHT CURE 20x0.28g TIPS OA2 OPT1294	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE 20x0.28g TIPS OA3.5 OPT1296	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE COMPOSITE SY 4g A1 OPT437	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE COMPOSITE SY 4g A2 OPT135	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE COMPOSITE SY 4g A3 OPT133	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE COMPOSITE SY 4g A3.5 OPT134	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE COMPOSITE SY 4g A4 OPT810	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE COMPOSITE SY 4g B1 OPT520	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE COMPOSITE SY 4g B2 OPT521	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE COMPOSITE SY 4g B3 OPT574	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE COMPOSITE SY 4g C1 OPT631	Ila	No	-	29 June 2018

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	MICRO HYBRID LIGHT CURE COMPOSITE SY 4g C2 OPT575	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE COMPOSITE SY 4g C3 OPT780	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE COMPOSITE SY 4g D2 OPT743	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE COMPOSITE SY 4g D3 OPT744	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE COMPOSITE SY 4g INCISAL OPT522	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE COMPOSITE SY 4g OA1 OPT633	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE COMPOSITE SY 4g OA2 OPT634	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE COMPOSITE 4g x 2 SY OPT534	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE COMPOSITE 4g x 5 SY OPT593	Ila	No	-	29 June 2018
	MICRO HYBRID LIGHT CURE COMPOSITE 4g x 7 SY OPT592	Ila	No	-	29 June 2018

Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	MICRO HYBRID LIGHT CURE 7x4g + Flow 2g + 3ml D/E + 6g ETCH OPT336	Ila	No	-	29 June 2018
	NANO HYBRID LIGHT CURE COMPOSITE SY 4g A1 OPT582	Ila	No	-	29 June 2018
	NANO HYBRID LIGHT CURE COMPOSITE SY 4g A2 OPT583	Ila	No	-	29 June 2018
	NANO HYBRID LIGHT CURE COMPOSITE SY 4g A3 OPT584	Ila	No	-	29 June 2018
	NANO HYBRID LIGHT CURE COMPOSITE SY 4g A3.5 OPT585	Ila	No	-	29 June 2018
	NANO HYBRID LIGHT CURE COMPOSITE SY 4g B1 OPT861	Ila	No	-	29 June 2018
	NANO HYBRID LIGHT CURE COMPOSITE SY 4g B2 OPT862	Ila	No	-	29 June 2018
	NANO HYBRID LIGHT CURE COMPOSITE SY 4g B3 OPT863	Ila	No	-	29 June 2018
	NANO HYBRID LIGHT CURE COMPOSITE SY 4g C1 OPT864	Ila	No	-	29 June 2018
	NANO HYBRID LIGHT CURE COMPOSITE SY 4g C2 OPT865	Ila	No	-	29 June 2018
	NANO HYBRID LIGHT CURE COMPOSITE SY 4g C3 OPT866	Ila	No	-	29 June 2018
	NANO HYBRID LIGHT CURE COMPOSITE SY 4g D2 OPT867	Ila	No	-	29 June 2018
	NANO HYBRID LIGHT CURE COMPOSITE SY 4g D3 OPT868	Ila	No	-	29 June 2018

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Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	NANO HYBRID LIGHT CURE COMPOSITE SY 4g INCISAL OPT233	Ila	No	-	29 June 2018
	NANO HYBRID LIGHT CURE COMPOSITE SY 4g OA2 OPT1064	Ila	No	-	29 June 2018
	NANO HYBRID LIGHT CURE COMPOSITE SY 4g OPT189	Ila	No	-	29 June 2018
	NANO HYBRID LIGHT CURE COMPOSITE SY 4.5g A1 OPT1107	Ila	No	-	29 June 2018
	NANO HYBRID LIGHT CURE COMPOSITE SY 4.5g A2 OPT1108	Ila	No	-	29 June 2018
	NANO HYBRID LIGHT CURE COMPOSITE SY 4.5g A3 OPT1109	Ila	No	-	29 June 2018
	NANO HYBRID LIGHT CURE COMPOSITE 4g x 2 SY OPT1031	Ila	No	-	29 June 2018
	NANO HYBRID LIGHT CURE COMPOSITE 4g x 5 SY OPT860	Ila	No	-	29 June 2018
	NANO HYBRID LIGHT CURE COMPOSITE 4g x 7 SY OPT588	Ila	No	-	29 June 2018
	NANO HYBRID LIGHT CURE COMPOSITE 4g x 7 SY + 9g etch + 3ml D/E OPT054	Ila	No	-	29 June 2018
	NANO HYBRID LIGHT CURE 7x4g + Flow 2g + 6ml D/E + 6g ETCH OPT348	Ila	No	-	29 June 2018
	FLOWABLE COMPOSITE 2g SY A1 OPT614	Ila	No	-	29 June 2018
	FLOWABLE COMPOSITE 2g SY A2 OPT615	Ila	No	-	29 June 2018

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Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	FLOWABLE COMPOSITE 2g SY A3 OPT616	Ila	No	-	29 June 2018
	FLOWABLE COMPOSITE 2g SY A3.5 OPT851	Ila	No	-	29 June 2018
	FLOWABLE COMPOSITE 2g SY A4 OPT1300	Ila	No	-	29 June 2018
	FLOWABLE COMPOSITE 2g SY B1 OPT239	Ila	No	-	29 June 2018
	FLOWABLE COMPOSITE 2g SY B2 OPT1001	Ila	No	-	29 June 2018
	FLOWABLE COMPOSITE 2g SY B3 OPT1002	Ila	No	-	29 June 2018
	FLOWABLE COMPOSITE 2g SY OA2 OPT1063	Ila	No	-	29 June 2018
	FLOWABLE COMPOSITE KIT 3x2g + 2ml etch OPT745	Ila	No	-	29 June 2018
	FLOWABLE COMPOSITE 3x2g + 2ml etch CLIP OPT754	Ila	No	-	29 June 2018
	FLOWABLE COMPOSITE KIT 4x2g OPT664	Ila	No	-	29 June 2018
	FLOWABLE COMPOSITE 4x2g CLIP OPT735	Ila	No	-	29 June 2018
	ENAMEL ETCHANT BLUE GEL SY 2.5ml OPT949	Ila	No	-	29 June 2018
	ENAMEL ETCHANT BLUE GEL SY 5g OPT1029	Ila	No	-	29 June 2018
	ENAMEL ETCHANT BLUE GEL SY 12g OPT694	Ila	No	-	29 June 2018

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Product category	Type/Model designation	Class	Sterile	GMDN code (not mandatory)	Date added
	ENAMEL ETCHANT GREEN GEL SY 12g OPT613	Ila	No	-	29 June 2018
	ENAMEL ETCHANT BLUE GEL SY 50ml OPT713	Ila	No	-	29 June 2018
	ENAMEL ETCHANT 4x2ml CLIP OPT894	Ila	No	-	29 June 2018
	ENAMEL ETCHANT 4x2.5ml CLIP OPT1216	Ila	No	-	29 June 2018
	ORTHODONTIC ADHESIVE SELF CURE 5g CLIP OPT687	Ila	No	-	29 June 2018
	ORTHODONTIC ADHESIVE SELF CURE 5g KIT OPT683	Ila	No	-	29 June 2018
	ORTHODONTIC ADHESIVE SELF CURE 2x5g OPT1041	Ila	No	-	29 June 2018
	ORTHODONTIC ADHESIVE SELF CURE KIT 2x3.5g OPT595	Ila	No	-	29 June 2018
	ORTHODONTIC ADHESIVE LIGHT CURE 5g CLIP OPT084	Ila	No	-	29 June 2018
	ORTHODONTIC ADHESIVE LIGHT CURE 2x5g OPT1042	Ila	No	-	29 June 2018
	ORTHODONTIC ADHESIVE LIGHT CURE KIT 2x3.5g OPT768	Ila	No	-	29 June 2018
	ORTHODONTIC ADHESIVE LIGHT CURE SY 5g (BOX) OPT350	Ila	No	-	29 June 2018
	ORTHODONTIC ADHESIVE LIGHT CURE SY 3.5g (BOX) OPT709	Ila	No	-	29 June 2018
	PIT & FISSURE SEALANT SELF CURE 12g OPT693	Ila	No	-	29 June 2018

Product category	Type/Model designation	Class	Sterile	GMDN code <small>(not mandatory)</small>	Date added
	PIT & FISSURE SEALANT LIGHT CURE SY 2g OPT910	Ila	No	-	29 June 2018
	PIT & FISSURE SEALANT LIGHT CURE 3x2g + 2ml etch CLIP OPT654	Ila	No	-	29 June 2018
	PIT & FISSURE SEALANT LIGHT CURE KIT 3x2g + 2ml etch OPT679	Ila	No	-	29 June 2018
	PIT & FISSURE SEALANT LIGHT CURE KIT 4x2g OPT635	Ila	No	-	29 June 2018

Sign Date: 8 May 2020
Valid Date: 19 May 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.

Certificate No: 41377502-01
Date: 8 May 2020
Handled by: Caroline Åman
E-mail: medtechsweden@intertek.com

Medental International

Attn: Gerard Kaim
José María Bustillos No. 28 Bis, 1er y 2do piso. Colonia Algarín,
Delegación Cuauhtémoc, CP. 06880. Ciudad de México,
México.

- Purpose** Assessment to issue a new certificate due to five year extension and address change. The old address was:
Jose Ma. Bustillos NO. 28-BIS, Col. Algarin, Mexico City, Distrito Federal 06880, Mexico
- Decision was made according to the national legislation for medical devices LVFS 2003:11 (Medical Device Directive 93/42/EEC), Annex V.
- Activity** Certification audit was performed 7 April 2020 in “Ciudad de México” by Juan Zamora.
The technical file was reviewed 22 October 2019 by Lian Zhangat Intertek’s office.
- Scope of assessment** - Dental materials, Class IIa
- Result** 0 non conformities were noted during the audit.
- Certificate Valid from** 19 May 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 V 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