

## Atitikties deklaracija Odontologinėms medžiagoms

### Europos Bendrijų Tarybos Direktyva 93/42/EEB su pakeitimais, padarytais 2007/47/EB dėl medicinos prietaisų, kurių valstybės narės perkėlė į Europos nacionalinę teisę

Toliau pasirašęs asmuo pareiškia, kad šiame dokumente aprašyti gaminiai atitinka jiems taikomas Tarybos direktyvos nuostatas ir gali būti ženklinami CE ženklu.

Bendras produkto pavadinimas:	Odontologinės medžiagos
Teisėtas gamintojas:	Dentonics, Inc. 2833 Tophill Road, Monroe, NC 28110 USA
Variantai:	Kaip nurodyta II priede (Šiame dokumente) – Produktų sąrašas/sąrašas
Numatoma paskirtis:	Naudojamas dantų struktūrai paruošti, taisyti, formuoti ir apsaugoti, dantų protezams surišti ir estetikai gerinti
MDD klasifikacija:	II(a) klasė
Notifikuotoji įstaiga:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam. Notified Body Number 2797
CE Sertifikato numeris:	CE 623238
ES autorizuotas atstovas:	Advena Limited. Tower Business Centre, 2 <sup>nd</sup> Flr., Tower Street, Swatar, BKR 4013 Malta.
MDD atitikties vertinimo būdas:	EC atitikties deklaracija pagal Medicinos prietaisų direktyva kartu su gamybos kokybės užtikrinimu apibūdintas V priede

Vardas Nola Benstog Pozicija Quality

Pasirašyta Data 03 Vasaris 2021

Kas yra fizinis ir juridinis asmuo, atsakingas už prietaiso projektavimą, gamybą, įpakavimą ir ženklimą etiketėmis prieš pateikiant jį rinkai šio gamintojo vardu, nepriklausomai nuo to, ar šiuos veiksmus atlieka gamintojas, ar jo pavedimu trečioji šalis.

## Declaration of Conformity

for Dental Materials

**European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states**

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

<b>General Product Name:</b>	Dental Materials
<b>Legal Manufacturer:</b>	Dentonics, Inc. 2833 Tophill Road, Monroe, NC 28110 USA
<b>Variants:</b>	As per Appendix II (This document) – Product Listing/Schedule
<b>Intended Use:</b>	Used to prepare, repair, shape and protect tooth structure, bond dental prostheses and improve aesthetics
<b>MDD Classification:</b>	Class II(a)
<b>Notified Body:</b>	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam. Notified Body Number 2797
<b>CE Certificate Reference:</b>	CE 623238
<b>EU Authorised Representative:</b>	Advena Limited. Tower Business Centre, 2 <sup>nd</sup> Flr., Tower Street, Swatar, BKR 4013 Malta.
<b>MDD Conformity Assessment Route:</b>	EC Declaration of Conformity in accordance with Annex VII of the Medical Device Directive coupled with Production Quality Assurance outlined in Annex V

**Name** Nola Benstog **Position** Quality

**Signed**  **Date** 03 February 2021

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

## Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied

## Appendix II – Product Listing/Schedule

Part / Catalogue Number	Description/Name	GMDN Code
10-000-KW	MASTER-DENT ZINC PHOS CEMENT WHITE (32g/17.5ml)	16710
10-000-KY	MASTER-DENT ZINC PHOS CEMENT YELLOW (32g/17.5ml)	16710
10-058	MASTER-DENT ZINC PHOS CEMENT YELLOW (80g/55g)	16710
10-200	MASTER-DENT POLYCARBOXYLATE CEMENT (25g/15ml)	16705
10-300	MASTER-DENT POLYCARBOXYLATE CEMENT (60g/40g)	16705
10-304	MASTER-DENT POLYCARBOXYLATE CEMENT (80g/40g)	16705
10-400	MASTER-DENT GLASS IONOMER CEMENT (15g/15ml)	16704
10-470	MASTER-DENT GLASS IONOMER LUTING CEMENT (35g/35ml)	16704
10-500	MASTER-DENT GLASS IONOMER CEMENT (50g/55ml)	16704
10-700	MASTER-DENT GLASS IONOMER CEMENT (100g/60ml)	16704
10-770	MASTER-CEM GLASS IONOMER CEMENT (15g/15ml)	16704
10-775	MASTER-DENT GLASS IONOMER CEMENT/LINER ONE-COMPONENT LIGHT CURE (5g SYR.)	16704
10-820	MASTER-DENT RESIN CEMENT SELF CURE AUTOMIX (7ml SYR. W/ 6 TIPS)	31750
10-830	MASTER-DENT RESIN CEMENT DUAL CURE AUTOMIX (10g SYR. W/ 6 TIPS)	31750
10-900	MASTER-DENT ZOE CEMENT (21g/7.5ml)	35875
10-910	MASTER-DENT REINFORCED ZOE CEMENT (50g/15ml)	35875
10-912	MASTER-DENT REINFORCED ZOE CEMENT (20g/10ml)	35875
10-920	MASTER-DENT TEMPORARY CEMENT NON-EUGENOL XS (5g SYR. PART A, 5g SYR. PART B, ACCESSORIES)	16709
10-922	MASTER-DENT TEMPORARY CEMENT NON-EUGENOL AUTOMIX (7g SYR. W/ 6 TIPS)	16709
10-928	MASTER-DENT TEMPORARY CEMENT ZINC OXIDE EUGENOL AUTOMIX (7ml SYR. W/ 6 TIPS)	16709
10-932	MASTER-DENT TEMPORARY CEMENT NON-EUGENOL XS AUTOMIX (8g SYR. W/ 6 TIPS)	16709
11-000	MASTER-DENT GLASS IONOMER LINER/BASE (15g/15ml)	16704

11-050	MASTER-DENT GLASS IONOMER LINER/BASE LIGHT CURE RESIN MODIFIED (15g/7ml)	16704
11-200N	MASTER-DENT CAVITY LINER LIGHT CURE (8g SYR.)	16182
11-254N	MASTER-DENT CAVITY LINER LIGHT CURE (4 X 1.5g SYR W/20 TIPS)	16182
11-275	MASTER-DENT CALCIUM HYDROXIDE POWDER (45g)	36095
11-276	MASTER-DENT CALCIUM HYDROXIDE POWDER (1 lb/454g)	36095
11-280	MASTER-DENT CALCIUM HYDROXIDE PASTE KIT (4x1g SYR W/8 TIPS)	36095
11-300	MASTER-DENT COPAL-PLUS CAVITY VARNISH (15ml)	35698
11-301	MASTER-DENT COPAL-PLUS SOLVENT (15ml)	35698
11-302	MASTER-DENT COPAL-PLUS CAVITY VARNISH (15ML) & COPAL VARNISH SOLVENT (15ML)	35698
11-402	MASTER-DENT TEMPORARY FILLING MAT. (38g JAR)	35870
11-405	MASTER-DENT TEMPORARY FILLING MAT. (28g JAR)	35870
11-500	MASTER-DENT TEMPORARY FILLING MAT. LIGHT CURE (4g SYR.)	35870
12-103	MASTER-DENT PIT & FISSURE SEALANT LC CLEAR KIT (2x7ml BOTTLES)	31780
12-104	MASTER-DENT PIT & FISSURE SEALANT LC OPAQUE KIT (2x7ml BOTTLES)	31780
12-155	MASTER-DENT PIT & FISSURE SEALANT LC CLEAR (4 X 1.2gM SYR. & 1 X 9 gM ETCH)	31780
12-156	MASTER-DENT PIT & FISSURE SEALANT LC OPAQUE (4 X 1.2gM SYR. & 1 X 9 gM ETCH)	31780
12-651	MASTER-DENT EUGENOL USP GRADE (1oz/30ml)	16709
12-655	MASTER-DENT EUGENOL USP GRADE (4oz/120ml)	16709
12-675	MASTER-DENT ROOT CANAL SEALER/CEMENT (40g/15ml)	36095
12-677	MASTER-DENT ROOT CANAL SEALER/CEMENT (10g/6ml)	36095
12-685	MASTER-DENT N-METHASONE ROOT CANAL SEALER (14g/10ml)	36095
12-695	MASTER-DENT ROTH ROOT CANAL SEALER POWDER (20G)	36095
12-700	MASTER-DENT ZINC OXIDE POWDER (454g)	16709
12-750	MASTER-DENT EDTA SOLUTION, 17% (2 oz/60ml)	45840
12-800	MASTER-DENT EDTA SOLUTION, 17% (8 oz/240ml)	45840
12-900	MASTER-DENT MTA ROOT & PULP TREATMENT MATERIAL (2g KIT)	60510
12-901	MASTER-DENT MTA ROOT & PULP TREATMENT MATERIAL (1g KIT)	60510
14-275	MASTER-DENT PASTE-PASTE COMPOSITE KIT WITH ETCH/BONDING (7g/7g)	38764
14-300	MASTER-DENT PASTE-PASTE COMPOSITE STANDARD KIT (14g/14g)	38764
14-400	MASTER-DENT PASTE-PASTE COMPOSITE KIT WITH ETCH/BONDING (14g/14g)	38764
15-421	MASTER-DENT GLASS IONOMER RESTORATIVE A2 (15g/10ml)	16704
15-422	MASTER-DENT GLASS IONOMER RESTORATIVE A3 (15g/10ml)	16704
15-500	MASTER-DENT GLASS IONOMER RESTORATIVE LIGHT CURE RESIN REINFORCED A2 (15g/7ml)	16704
15-501	MASTER-DENT GLASS IONOMER RESTORATIVE LIGHT CURE RESIN REINFORCED A3 (15g/7ml)	16704
15-600	MASTER-DENT GLASS IONOMER RESTORATIVE POSTERIOR (15g/7ml)	36095
18-100	MASTER-DENT ETCH GEL GREEN (12g W/ TIPS)	36153
18-105	MASTER-DENT ETCH GEL GREEN (60g SYR. W/5 EMPTY 3ml SYRINGES AND 50 TIPS)	36153

18-114	MASTER-DENT ETCH GEL GREEN (12g SYR. W/ 20 LUER LOCK TIPS)	36153
18-120	MASTER-DENT ETCH GEL BLUE (12g SYR. W/ 20 LUER LOCK TIPS)	36153
18-124	MASTER-DENT ETCH GEL BLUE (4 x 3ml SYR. W/ 20 LUER LOCK TIPS)	36153
18-125	MASTER-DENT ETCH GEL BLUE (4 x 1.2ml SYR. W/ 20 LUER LOCK TIPS)	36153
18-130	MASTER-DENT ETCH GEL BLUE (60g SYR. W/5 EMPTY 3ml SYRINGES W/ 50 LUER LOCK TIPS)	36153
18-400-L	MASTER-DENT LIQUID ETCH (9g)	36153
18-400-V	MASTER-DENT VISCOUS ETCH (9g)	36153
18-500-L	MASTER-DENT LIQUID ETCH (1oz/30ml)	36153
18-500-V	MASTER-DENT VISCOUS ETCH (1oz/30ml)	36153
18-600-L	MASTER-DENT LIQUID ETCH (2oz/60ml)	36153
18-600-V	MASTER-DENT VISCOUS ETCH (2oz/60ml)	36153
18-650-L	MASTER-DENT LIQUID ETCH (8oz/240ml)	36153
18-650-V	MASTER-DENT VISCOUS ETCH 8oz/240ml)	36153
18-700-L	MASTER-DENT LIQUID ETCH (12oz/360ml)	36153
18-700-V	MASTER-DENT VISCOUS ETCH (12oz/360ml)	36153
19-000-N	MASTER-DENT CORE BUILD-UP MATERIAL CHEMICAL CURE, NATURAL (14g/14g)	38789
19-152	MASTER-DENT CORE BUILD-UP MATERIAL DUAL CURE A2 (25ml CART., W/3 TIPS)	38789
19-155	MASTER-DENT CORE BUILD-UP MATERIAL CHEMICAL CURE, NATURAL (50ml CART. W/ 10 TIPS)	38789
19-215	MASTER-DENT ULTIMATE BOND LC (7g)	42483
19-215-B	MASTER-DENT ULTIMATE DENTIN/ENAMEL BOND BULK (KG)	42483
19-280	MASTER-DENT ULTIMATE SE BOND LC (7g)	42483
19-380	MASTER-DENT MASTER-FIL MICRO HYBRID KIT (4X4.5g,A1,A2,A3,B2 & ULTIMATE BOND 7g, 3ml ETCH GEL SYR.)	38764
19-381	MASTER-DENT MASTER-FIL MICRO HYBRID A1 (4.5g SYR.)	38764
19-381-C	MASTER-DENT MASTER-FIL MICRO HYBRID CAPSULES A1 (20 X 0.25g)	38764
19-382	MASTER-DENT MASTER-FIL MICRO HYBRID A2 (4.5g SYR.)	38764
19-382-C	MASTER-DENT MASTER-FIL MICRO HYBRID CAPSULES A2 (20 X 0.25g)	38764
19-383	MASTER-DENT MASTER-FIL MICRO HYBRID A3 (4.5g SYR.)	38764
19-383-C	MASTER-DENT MASTER-FIL MICRO HYBRID CAPSULES A3 (20 X 0.25g)	38764
19-384	MASTER-DENT MASTER-FIL MICRO HYBRID A3.5 (4.5g SYR.)	38764
19-384-C	MASTER-DENT MASTER-FIL MICRO HYBRID CAPSULES A3.5 (20 X 0.25g)	38764
19-386	MASTER-DENT MASTER-FIL MICRO HYBRID B1 (4.5g SYR.)	38764
19-386-C	MASTER-DENT MASTER-FIL MICRO HYBRID CAPSULES B1 (20 X 0.25g)	38764
19-387	MASTER-DENT MASTER-FIL MICRO HYBRID B2 (4.5g SYR.)	38764
19-387-C	MASTER-DENT MASTER-FIL MICRO HYBRID CAPSULES B2 (20 X 0.25g)	38764
19-412-A1	MASTER-DENT FLOW COMPOSITE A1 (2 X 2g W/TIPS, POUCH)	38764
19-412-A2	MASTER-DENT FLOW COMPOSITE A2 (2 X 2g W/TIPS, POUCH)	38764
19-412-A3	MASTER-DENT FLOW COMPOSITE A3 (2 X 2g W/TIPS, POUCH)	38764
19-412-A3.5	MASTER-DENT FLOW COMPOSITE A3.5 (2 X 2g W/TIPS, POUCH)	38764
19-412-B1	MASTER-DENT FLOW COMPOSITE B1 (2 X 2g W/TIPS, POUCH)	38764
19-412-B2	MASTER-DENT FLOW COMPOSITE B2 (2 X 2g W/TIPS, POUCH)	38764

19-412-C3	MASTER-DENT FLOW COMPOSITE C3 (2 X 2g W/TIPS, POUCH)	38764
19-412-D3	MASTER-DENT FLOW COMPOSITE D3 (2 X 2g W/TIPS, POUCH)	38764
19-412-G	MASTER-DENT FLOW COMPOSITE GINGIVAL (2 X 2g W/TIPS, POUCH)	38764
19-412-O	MASTER-DENT FLOW COMPOSITE OPAQUE (2 X 2g W/TIPS, POUCH)	38764
19-414-A1	MASTER-DENT FLOW COMPOSITE (A1 4 X 2g W/TIPS)	38764
19-414-A2	MASTER-DENT FLOW COMPOSITE (A2 4 X 2g W/TIPS)	38764
19-414-A3	MASTER-DENT FLOW COMPOSITE (A3 4 X 2g W/TIPS)	38764
19-414-A3.5	MASTER-DENT FLOW COMPOSITE (A3.5 4 X 2g W/TIPS)	38764
19-414-AS	MASTER-DENT FLOW COMPOSITE (1 EA. A1, A2, A3, C3) (4 X 2 g W/TIPS, BOXED)	38764
19-414-B1	MASTER-DENT FLOW COMPOSITE B1 (4 X 2g W/TIPS)	38764
19-414-B2	MASTER-DENT FLOW COMPOSITE B2 (4 X 2g W/TIPS)	38764
19-414-C3	MASTER-DENT FLOW COMPOSITE C3 (4 X 2g W/TIPS)	38764
19-414-D3	MASTER-DENT FLOW COMPOSITE D3 (4 X 2g W/TIPS)	38764
19-414-G	MASTER-DENT FLOW COMPOSITE GINGIVAL (4 X 2g W/TIPS)	38764
19-414-O	MASTER-DENT FLOW COMPOSITE OPAQUER (4 X 2g W/TIPS)	38764
19-501	MASTER-DENT MASTER-FIL NANO HYBRID A1 (4.5g SYR.)	38764
19-501-C	MASTER-DENT MASTER-FIL NANO HYBRID CAPSULES A1 (20 X 0.25g)	38764
19-502	MASTER-DENT MASTER-FIL NANO HYBRID A2 (4.5g SYR.)	38764
19-502-C	MASTER-DENT MASTER-FIL NANO HYBRID CAPSULES A2 (20 X 0.25g)	38764
19-503	MASTER-DENT MASTER-FIL NANO HYBRID A3 (4.5g SYR.)	38764
19-503-C	MASTER-DENT MASTER-FIL NANO HYBRID CAPSULES A3 (20 X 0.25g)	38764
19-602	MASTER-DENT MASTER-FIL BULKFILL (4.5g SYR.)	38789
27-001	MASTER-DENT ORTHO ADHESIVE LIGHT CURE PASTE (5g SYR.)	31750
27-001SP	MASTER-DENT ORTHO ADHESIVE LIGHT CURE PASTE, 5g *PUSH SYRINGE*)	31750
27-002	MASTER-DENT ORTHO ADHESIVE LIGHT CURE PRIMER REFILL (7g)	31750
27-003	MASTER-DENT ORTHO ADHESIVE LIGHT CURE ETCH REFILL (15ml)	31750
27-004	MASTER-DENT ORTHO ADHESIVE LIGHT CURE KIT (4 X 5g SYR.)	31750
27-004SP	MASTER-DENT ORTHO ADHESIVE LIGHT CURE KIT (4 X 5g *PUSH SYRINGES*)	31750
27-200	MASTER-DENT ORTHO ADHESIVE LIGHT CURE TRIAL KIT (5g)	31750
27-225	MASTER-DENT ORTHO BAND CEMENT LIGHT CURE SYRINGE (5g)	31750
27-340	MASTER-DENT ORTHO ADHESIVE NO-MIX PRIMER (6ml)	31750
27-355	MASTER-DENT ORTHO ADHESIVE NO-MIX (5g SYR)	31750
27-500	MASTER-DENT ORTHO ADHESIVE NO-MIX TRIAL KIT (1 X 5g)	31750
27-600	MASTER-DENT ORTHO ADHESIVE NO-MIX PRIMER (16 ml)	31750
32-600	MASTER-DENT PORCELAIN PRIMER (15ml)	31750
60-200	MASTER-DENT TEMP C&B MATERIAL A2 (50ml CARTR. W/10 TIPS)	31783
60-201	MASTER-DENT TEMP C&B MATERIAL A3 (50ml CARTR. W/10 TIPS)	31783
60-202	MASTER-DENT TEMP C&B MATERIAL B1 (50ml CARTR. W/10 TIPS)	31783
60-203	MASTER-DENT TEMP C&B MATERIAL A1 (50ml CARTR. W/10 TIPS)	31783

## Version History

Version	Compiled by	Date	Description
1.0	David Zou	03 February 2021	First issue