

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.

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| 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 nd 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.

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

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| 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 |

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| 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 |

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| 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 |
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