



Making Dentistry Easier.SM

Centrix Incorporated

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EC DECLARATION OF CONFORMITY FOR MEDICAL DEVICES

In accordance with the Essential Requirements of Annex I and the pertinent requirements of Annex VII of the Medical Devices Directive 93/42/EEC as amended by 2007/47/EEC

Name of Manufacturer:

Centrix Inc.

Address:

770 River Road, Shelton, CT 06484

Name of authorized representative in the European Union:

Sven Albersmann

Address:

Dental-Contact Vertriebs OHG

Im Spiet 101

We declare that the following product part numbers conform to the regulations of 93/42/EEC for Medical Devices as amended by 2007/47/EEC:

Class: IIa

Greg Moreau

3-Mar-2021

Director, Quality Assurance/Regulatory Affairs

REF	DESC
see attached list	

Class IIa Declaration of Conformity Attachment

290040:	NOMIX® SYRINGE REFILL, 12
290051:	MICROASPIRATORS®, 18 GA, 24
290052:	MICROASPIRATORS®, 20 GA, 24
310015	ABSOLUTE UNIVERSAL RESIN CEMENT
310016	ABSOLUTE ASSORTED RESIN CEMENT
310031:	TEMPIT® E
310052:	ONYX™, 25 SYRINGES
310053:	ONYX™ ETCH KIT, 6 SYRINGES & 30 NEEDLES
310054:	ONYX™ ETCH KIT, 15 SYRINGES & 50 NEEDLES
310055:	ONYX™ ETCH KIT, 15 SYRINGES & 100 NEEDLES
310060:	TEMPIT®, .35GR, 30
310063:	TEMPIT® L/C, .25GR, 30
310064:	TEMPIT® ULTRA F, .20GR, 30
310065:	TEMPIT® ULTRA, .20GR, 30
310067:	TEMPIT® ESSENTIALS
310070:	ENCORE® WITH FLUORIDE
310071:	C-R® HYBRID SELF CURE
310075:	ENCORE® WITHOUT FLUORIDE
310076:	ENCORE® NATURAL WITH FLUORIDE
310077:	ENCORE® NATURAL W/O FLUORIDE
310093:	ENCORE® AF WHITE W/ FLUORIDE
310094:	ENCORE® AF NAT W/ FLUORIDE
310106:	D/SENSE® CRYSTAL™
310113	ABSOLUTE OPAQUE RESIN CEMENT
310114	ABSOLUTE TRANSLUCENT RESIN CEMENT
310122:	GLU/SENSE™ KIT
310129:	ENCORE® DC MINIMIX, NATURAL, 12
310130:	ENCORE® DC MINIMIX, CONTRAST, 12
310136:	RAPIDCORE™, 25ML WHITE
310137:	RAPIDCORE™, 25ML NATURAL
310140:	SUPERCURE®, NAT, .25gr, 30
310141:	SUPERCURE®, NAT, .5gr, 30
310142:	SUPERCURE®, CON, .25gr, 30
310143:	SUPERCURE®, CON, .5gr, 30
310146:	SUPERCURE® Q, NAT, .5gr, 30
310147:	SUPERCURE® Q, CON, .5gr, 30
310150:	ENCORE® DC, NAT, WITH FLUORIDE
310152:	ENCORE® DC, CON, WITH FLUORIDE
310157:	NOMIX® TAKE HOME CARD DISPENSER
310254:	ENCORE® D/C MINI MIX NAT 36
310255	ENCORE® D/C MINI MIX CONT 36
310270:	CONNEXIO SELF-ETCH BONDING AGENT
310521:	ACCESS TEMP CEMENT
310520:	NOMIX® STARTER KIT
320003:	CALCIJECT™, .20GR, 24
330501:	VERSAFLO® 16PK, A1
330502:	VERSAFLO® 16PK, A2
330503:	VERSAFLO® 16PK, A3
330504:	VERSAFLO® 16PK, A3.5
330508:	VERSAFLO® 16PK, OP

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330509: VERSAFLO® 16PK, B1
330520: VERSAFLO® SYRINGE KIT, A1
330521: VERSAFLO® SYRINGE KIT, A2
330522: VERSAFLO® SYRINGE KIT, A3
330530: VERSAFLO® SINGLE SYRINGE, A1
330531: VERSAFLO® SINGLE SYRINGE, A2
330600: VERSALITE®, 20PK, A1
330601: VERSALITE®, 20PK, A2
330609: VERSALITE®, 20PK, C3
330610: VERSALITE®, 20PK, A3
360029: ACCESS CROWN®, A3.5
360030: ACCESS CROWN®, A3
360031: ACCESS CROWN®, B1
360034: ACCESS CROWN®, A2
360035: ACCESS CROWN®, A1
360037: ACCESS CROWN®, C2
360038: ACCESS CROWN®, BLEACH
360077: FLUORODOSE™ BUBBLE GUM, 600
360078: FLUORODOSE™ MINT, 600
360086: FLUORODOSE™ MINT, 120
360087: FLUORODOSE™ BUBBLE GUM, 120
360105: FLUORODOSE™ MINT, 1200
360106: FLUORODOSE™ BUBBLE GUM, 1200
360107: FLUORODOSE™ MELON, 120
360108: FLUORODOSE™ MELON, 600
360109: FLUORODOSE™ MELON, 1200
360110: FLUORODOSE™ CHERRY, 120
360111: FLUORODOSE™ CHERRY, 600
360112: FLUORODOSE™ CHERRY, 1200
360116: CHAMP SEALANT, 16
360120: CHAMP SEALANT, 64
360137: FLUORODOSE™ CARAMEL, 120
360138: FLUORODOSE™ CARAMEL, 600
360139: FLUORODOSE™ CARAMEL, 1200
360221: FLUORODOSE™ ASSORTED, 600
360222: FLUORODOSE™ ASSORTED, 120
700000: ENCORE® DC MINIMIX KIT, NATURAL, 12
700001: FLUORODOSE™ FLAVOR, 32