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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 II 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:

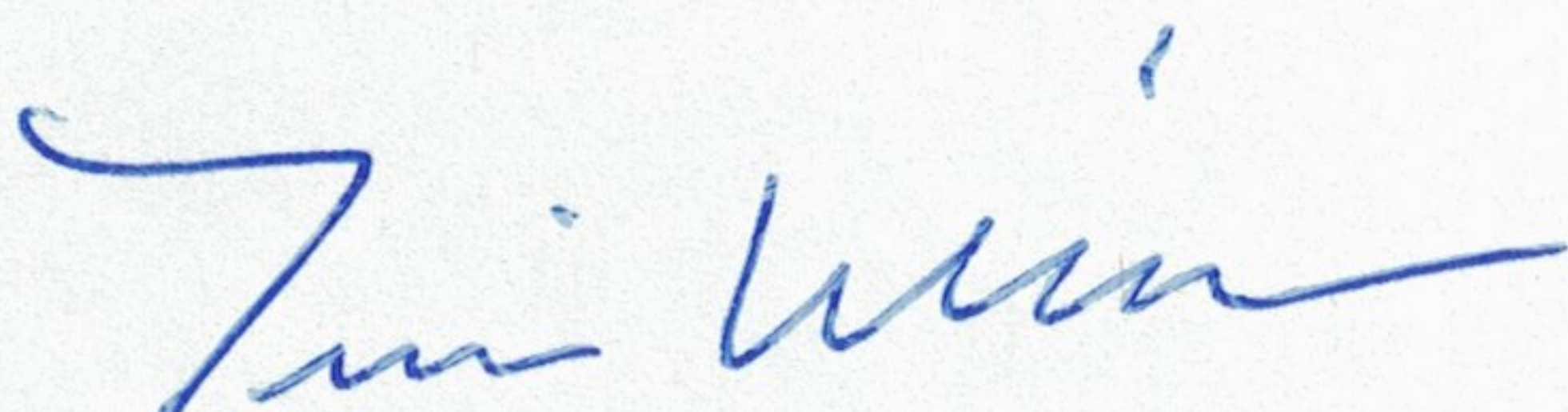
Dental-Contact Vertriebs OHG

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

CE Certificate No.: **7282GB410200205**

 **MARCH 26, 2024**

Tim White
RA Manager

26-Mar-2024

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 SELFCURE
 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

Class IIa Declaration of Conformity Attachment

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