

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: I


Greg Moreau

30-Oct-2018

Director, Quality Assurance/Regulatory Affairs

REF	DESC
see attached list	

Declaration of Conformity Attachment

REF	DESCRIPTION
100007:	IMP. CLEANING BRUSHES (5)
100008:	IMP O-RINGS SILICONE (6)
100031:	NUGUN® PLUNGER/SPRING
100033:	MKIIP™ PLUNGER/SPRING
100034:	S-CLASS® PLUNGER/SPRING
100035:	JUMBO® PLUNGER/SPRING
100036:	C-R® EZ PLUNGER, SPRING
110000:	MK I™ SYRINGE ONLY
110007:	BARREL SYRINGE HANDLE
110009:	IMPRESSION SYRINGE ONLY
110010:	STANDARD IMPRESSION SYRINGE KIT
110615:	MK I™ ACCUDOSE® STARTER KIT
120000:	MK II™ SYRINGE ONLY
120615:	MK II™ ACCUDOSE® STARTER KIT
130600:	MK IIP™ SPEED SLOT SYRINGE
130615:	MK IIP™ ACCUDOSE® STARTER KIT
130650:	SNAP FIT™ SYRINGE
130651:	SNUB NOSE SNAP FIT™ SYRINGE
130700:	MKIIP™ E/Z® SYRINGE
130715:	MKIIP™ E/Z® STARTER KIT
130730:	MKIIP™ E/Z® SYRINGE BLUE
140000	MARK II SNAPFIT SYRINGE
140615	MARK II SNAPFIT SYRINGE KIT
160600:	NUGUN® ONLY
160615:	NUGUN® ACCUDOSE® STARTER KIT
170600:	S-CLASS® ONLY
170615:	S-CLASS® ACCUDOSE® STARTER KIT
180600:	JUMBO® SYRINGE ONLY
180615:	JUMBO® TUBE STARTER KIT
210000:	RUBBER PLUGS, 100
210001:	SEPARATE TUBE & PLUG, 100
210003:	SEPARATE TUBE & PLUG, 500
210021:	LOW VISC ACCUDOSE® TUBE & PLUG, 100
210023:	LOW VISC ACCUDOSE® TUBES & PLUGS, 500
220000:	GREEN PLUGS, 100
220002:	BLUNT NOSE PLUG, 100
240001:	BLACK TUBES & PLUGS, 100
250001:	OPAQUE PCR™ TUBE & PLUG, 100
250003:	OPAQUE PCR™ TUBE & PLUG, 500
250011:	CLEAR PCR™ TUBE & PLUG, 100
270007:	BLACK TUBES & PLUGS, 500
280021:	HI VISC ACCUDOSE® TUBES & PLUGS, 100
280023:	HI VISC ACCUDOSE® TUBES & PLUGS, 500
290016:	STD TIPS, 18 GA, WHITE, 144
290017:	IMP. TIPS, 18 GA, YELLOW, 144
290019:	STD TIPS, 18 GA, WHITE, 500
290020:	BARREL SYR, 1 HAND & 72 BAR
290021:	SYRINGE BARRELS ONLY, 144
290022:	IMP. TIPS, 20GA, AQUA, 144

290025: AUTOMIX TIPS, 18GA, GREEN, 144
290028: IMP TIPS, 18GA, YELLOW, 500
290031: ACCUDOSE® NEEDLETUBE™, 20 GA, 100
290032: ACCUDOSE® NEEDLETUBE™, 19 GA, 100
290033: ACCUDOSE® NEEDLETUBE™, 20 GA, 500
290035: ACCUDOSE® NEEDLETUBE™, 19 GA, 500
290038: SOFNEEDLE™, 144
290040: NOMIX® SYRINGE ONLY KIT
290041: ACCUDOSE® RIBBON TUBE, 100
290061: JUMBO® TUBE REFILL KIT
310156: DS25 1:1 AUTOMIX SYRINGE
310280: NOCORD VPS INTRO TRIAL KIT
310281: NOCORD VPS TRAY 2PK
310282: NOCORD VPS WASH 2PK
310283: NOCORD VPS TRAY 10PK
310284: NOCORD VOS WASH 10PK
310311: BENDA® MATIC DISPENSER
310322: EXPOSE™ BLUE INDICATOR KIT
310325: EXPOSE™ RED INDICATOR KIT
310330: EXPOSE™ FINE BLUE REFILL
310331: EXPOSE™ XFINE BLUE REFILL
310332: EXPOSE™ XFINE RED REFILL
310333: EXPOSE™ FINE REFILL
333000: VERSABOX™
333001: VERSA BOX™, 24 SEPARATORS
360001: ACCESS PURPLE®
360002: ACCESS GOLD®
360005: ACCESS® TRAY ADHESIVES
360006: ACCESS BLUE®
360010: SUPERMIXER TEAL 24PK
360011: 3.N.1™ TRAY, 35 ANTERIOR
360012: 3.N.1™ TRAY, 50 POSTERIOR
360013: 3.N.1™ TRAY, 35 QUADRANT
360014: 3.N.1™ TRAY, 40 ASSORTED
360015: ACCESS® PUTTY™
360016: ACCESS® HEAVY™
360017: ACCESS® MONOPHASE™
360036: DS50 1:1/2:1 AUTOMIX SYRINGE
360054: ZIP-ZIP-GO™ POLISHER KIT
360056: GINGITRAC™, ONLY, REG, LG
360068: GINGITRAC™ MINIMIX STARTER
360069: GINGITRAC™ MINIMIX REFILL
360100: GINGITRAC™ REFILL 1:1
360101: GINGITRAC™ STANDARD 1:1
360102: GINGITRAC™ PLUS 1:1
360103: GINGITRAC™ REG REFILL KIT
360104: GINGITRAC™ LARGE REFILL KIT
360113: ACCESS EDGE, 15
360114: ACCESS EDGE, 60
360122: ACCESS FLO, 15
360123: ACCESS FLO, 60
370101: BENDA® BRUSH REG MULTI, 144

370105:	BENDA TWIN®, PINK, 200
370106:	BENDA TWIN®, BLUE, 200
370107:	BENDA TWIN®, PINK, 400
370108:	BENDA TWIN®, BLUE, 400
370111:	MINI BENDA® BRUSH, 144 PACK
370260:	ISOVUE ANT. STARTER, 60
370261:	ISOVUE ANT. SMALL, 40
370262:	ISOVUE MEDIUM, 40
370263:	ISOVUE LARGE, 40
370264:	ISOVUE QUAD. STARTER, 60
370265:	ISOVUE QUAD. SMALL, 40
370266:	ISOVUE QUAD. MEDIUM, 40
370267:	ISOVUE QUAD. LARGE, 40
370501:	BENDA® BRUSH BIG BOX, REG RED, 576
370502:	BENDA® BRUSH BIG BOX REG BLUE, 576
370503:	BENDA® BRUSH BIG BOX REG YELLOW, 576
370504:	BENDA® BRUSH BIG BOX REG GREEN, 576
370601:	BENDA® BRUSH BIG BOX MINI RED, 576
370602:	BENDA® BRUSH BIG BOX MINI BLUE, 576
370603:	BENDA® BRUSH BIG BOX MINI YELLOW, 576
370604:	BENDA® BRUSH BIG BOX MINI GREEN, 576
380005:	BENDA® MICRO REG MULTI, 400
380006:	BENDA® MICRO FINE MULTI, 400
380012:	BENDA® MICRO FINE YELLOW, 576
380013:	BENDA® MICRO FINE RED, 576
380014:	BENDA® MICRO REG BLUE, 576
380015:	BENDA® MICRO REG GREEN, 576
380016:	BENDA® MICRO REG PURPLE, 576
380017:	BENDA® MICRO REG SILVER, 576
380020:	MICROTWIN® REG PINK 200
380021:	MICROTWIN® REG BLUE, 200
380022:	MICROTWIN® REG PINK, 400
380023:	MICROTWIN® REG BLUE, 400
380027:	MICROTWIN® XF IVORY, 400
380028:	MICROTWIN® XF GREEN, 400
380029:	BENDA® MICRO XF LT GREEN, 576
380030:	BENDA® MICRO XF IVORY, 576
380031:	BENDA® MICRO XF LT GREEN, 100
380032:	BENDA® MICRO XF IVORY, 100
380033:	BENDA® MICRO XF MULTI, 400
640001:	LUER LOCK NEEDLES, 22 GA, 100
640002:	NOMIX® SYRINGE TIPS, 30
830001:	LATCH MANDRELS, 10
830002:	PLASTIC MANDRELS, 24
840015:	MED YELLOW POINTS, 100
840016:	MED YELLOW CUPS, 100
840017:	MED YELLOW POINTS, 30
840018:	MEDIUM YELLOW CUPS, 30
840038:	COMP/MICRO START K. LATCH
840055:	FINE GREY POINTS, 100
840056:	FINE GREY CUPS, 100
840057:	FINE GREY POINTS, 30

840058:	FINE GREY CUPS, 30
850017:	GOLD/AMAL 30 BROWN POINTS
850018:	GOLD/AMAL 30 BROWN CUPS
850038:	GOLD/AMAL START KIT LATCH
850057:	GOLD/AMAL 30 GREEN POINTS
850058:	GOLD/AMAL 30 GREEN CUPS
850071:	X-FINE WHITE CUPS, 30
850072:	X-FINE WHITE POINTS, 30
850073:	X-FINE WHITE CUPS, 100
850074:	X-FINE WHITE POINTS, 100
860002:	PROXIDISCS®, ABRV 2 SIDE, 18
860003:	PROXIDISCS®, SMOOTH SIDE, 18
390010	COUTURE PROXIDISCS, DIAMOND
390011	COUTURE PROXIDISCS, SMOOTH
860010:	GRIPSTRIP, MEDIUM, 12
860011	GRIPSTRIP, COARSE, 12
860012	GRIPSTRIP, FINE, 12
860013	GRIPSTRIP, ASSORTED
870046:	ISOVUE SAMPLE
910004:	PLUNGER IIIP, STD, BLK
910010:	PLUNGER MK III, IMP
910012:	PLUNGER MK I, II BLK
910025:	NUGUN® PLUNGER ASSY
910034:	SPRING MKIII OR IV
910056:	HUB, IMP SYR POLISHED
910626:	S50 NOZZLES, BLUE HUB, 50
910628:	NOZZLE, YELLOW HUB, 50
910629:	GINGITRAC™ NOZZLES, 50
910630:	MINIMIX NOZZLES, 10
910631:	COMBO, MIXING NOZZLES, YELLOW HUB w/ TIP, 50
910632:	1:1 MIXING NOZZLES, 50 PK
915006:	GI SPRING
915043:	SNAP-FIT SYRINGE ASSY, NO PRINT LOGO
920201:	ACCUDOSE TRIPACK
950071:	TIP, SOFNEEDLE™ LUER LOC
950103:	1CC SYRINGE W/ BLACK PLUNGER
950104:	1CC SYRINGE CAP/BLACK