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Declaration of Conformity

Declaration Number: DC-I0-0502KSA Rev. A

Supplier: Integra LifeSciences Corporation
4900 Charlemar Drive, Building A
Cincinnati, Ohio 45227 USA

Catalog No: See Attachment 1



The devices listed in Attachment 1 are in conformity with:

Document No.	Document Title	Edition
MDD 93/42/EEC	Council Directive 93/42/EEC of 14 June 1993 concerning medical devices	June 14, 1993
MDD Amendment 2007/47/EC	Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007	September 5, 2007
ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes	2003
ISO 13485 (under CMDCAS)	Medical devices – Quality management systems – Requirements for regulatory purposes	2003

Additional information:

Certificate: Certificate for a Quality Management System to ISO 13485:2003
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Attachment 1

MAIN DEVICES:

Reference	Description	Classification (Directive 93/42/EEC, Annex IX)	
A1008	MAYFIELD GENERAL PURPOSE HEADREST	I	Rule 1
A1011	MAYFIELD HORSESHOE HEADREST	I	Rule 1
A1012	MAYFIELD SWIVEL HORSESHOE HEADREST	I	Rule 1
A1015	MAYFIELD CROSSBAR ADAPTOR	I	Rule 1
A1016	MAYFIELD CROSSBAR ADAPTOR (339,5 mm)	I	Rule 1
A1018	MAYFIELD SWIVEL ADAPTOR	I	Rule 1
A1023	MAYFIELD INSTRUMENT WALL STORAGE UNIT	I	Rule 1
A1051	MAYFIELD PEDIATRIC HORSESHOE HEADREST	I	Rule 1
A1059	MAYFIELD MODIFIED SKULL CLAMP	I	Rule 1
A1060	MAYFIELD UNIVERSAL SIDE RAIL FITTING	I	Rule 1
A1064	MAYFIELD BALL SOCKET SWIVEL ADAPTOR	I	Rule 1
A1073	PAPADOPOULOS P.C.S. SUPPORT	I	Rule 1
A1079	RADIOLUCENT BASE UNIT W/ADAPTORS	I	Rule 1
A1108	MAYFIELD TRIAD SKULL CLAMP	I	Rule 1
A1109	MAYFIELD HORSESHOE CONVERSION ADAPTOR	I	Rule 1
A1110	MAYFIELD HORSESHOE CONVERSION ADAPTOR W/KNOBS	I	Rule 1
A1111	RADIOLUCENT TRI-STAR SWIVEL ADAPTOR	I	Rule 1
A1112	MAYFIELD INFINITY SUPPORT SYSTEM	I	Rule 1
A1113	MAYFIELD NEUROGEN ADAPTOR	I	Rule 1
A1114	MAYFIELD INFINITY SKULL CLAMP	I	Rule 1
A1114A	BASIC MAYFIELD INFINITY SKULL CLAMP	I	Rule 1
A1115	MODIFIED SWIVEL ADAPTOR	I	Rule 1
A1116	MODIFIED TRI-STAR ADAPTOR	I	Rule 1
A1117	MR/X-Ray Skull Clamp	I	Rule 1
A2000	MAYFIELD 2000 SKULL CLAMP	I	Rule 1
A2002	MAYFIELD 2000 RADIOLUCENT SKULL CLAMP	I	Rule 1
A2003	MAYFIELD® 2000 Radiolucent Skull Clamp and Adaptor System	I	Rule 1
A2004	MAYFIELD 2000 RADIOLUCENT HEADREST SYSTEM	I	Rule 1
A2006	MAYFIELD MODIFIED RADIOLUCENT SKULL CLAMP	I	Rule 1
A2008	MAYFIELD TRI-STAR SWIVEL ADAPTOR	I	Rule 1
A2009	ULTRA 360 PATIENT POSITIONING SYSTEM	I	Rule 1
A2010	MAYFIELD ADULT RADIOLUCENT HORSESHOE HEADREST	I	Rule 1
A2011	MAYFIELD PEDIATRIC RADIOLUCENT HORSESHOE HEADREST	I	Rule 1
A2029	ULTRA 360 PATIENT POSITIONING SYSTEM - INTERNATIONAL	I	Rule 1
A2079	XR2 BASE UNIT ASSEMBLY	I	Rule 1
A2079E	MAYFIELD® Infinity XR2 Base Unit, Extended	I	Rule 1
A2101	MAYFIELD ULTRA BASE UNIT	I	Rule 1
A2102	MAYFIELD ULTRA BASE UNIT - INTERNATIONAL	I	Rule 1
A2111	XR2 TRI-STAR SWIVEL ADPTR	I	Rule 1
A2114	XR2 Skull Clamp	I	Rule 1
437A2224	XR2 EXTENSION Arm, 5" (127mm)	I	Rule 1



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437A2225	XR2 EXTENSION Arm, 5" (178mm)		Rule 1
439A1091	XR2 CHILD ROCKER ASSEMBLY		Rule 1
439A1092	XR2 METAL FREE CONVERSION		Rule 1
439A1093	XR2 ACCESSORY - FORCE MODULE		Rule 1
439A1094	XR2 ADULT ROCKER ASSEMBLY		Rule 1
439A1095	XR2 STANDARD TORQUE SCREW		Rule 1
A2600M	MAYFIELD SPINE TABLE ADAPTOR (STANDARD)		Rule 1
A2600R	MAYFIELD SPINE TABLE ADAPTOR (RADIOLUCENT)		Rule 1
A3008	MAYFIELD [®] 2 Tri-Star Swivel Adaptor		Rule 1
A3018	MAYFIELD [®] 2 Adaptor, Standard		Rule 1
A3059	MAYFIELD [®] 2 Skull Clamp		Rule 1
A3100	MAYFIELD [®] 2 Base Unit, Narrow		Rule 1
A3101	MAYFIELD [®] 2 Base Unit, Standard		Rule 1
A3102	MAYFIELD [®] 2 Base Unit, International		Rule 1

