



ZIMMER BIOMET

EU Declaration of Conformity

Declaration Number: EU7000.IIb, Revision B

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Legal Manufacturer, Authorized Representative and Notified Body Details	
Legal Manufacturer	Biomet Sports Medicine
Address of Legal Manufacturer	56 East Bell Drive P.O. Box 587 Warsaw, Indiana 46581 USA
Authorized Representative	Biomet GSCC B.V.
Address of Authorized Representative	Hazeldonk 6530 4836 LD Breda The Netherlands
Notified Body	BSI
Notified Body Number	2797
Notified Body Address	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam Netherlands

Declaration Statement
We hereby declare that the subject medical devices meet the provisions of Council Directive No. 93 / 42 / EEC for Medical Devices as amended by Directive 2007/47/EC. This Declaration of Conformity is hereby issued under the sole responsibility of the legal manufacturer specified herein.

Product Description	
Product Name	JuggerKnot Soft Anchor Implants
Device Details	Details in Appendix 1
Device Classification	IIb
Applicable Rule	Rule 8 of Annex IX of 93/42/EEC (EU Medical Device Directive)
Conformity Assessment Route	Full quality assurance system per Annex II of Council Directive 93/42/EEC, excluding section 4 (design examination)
Intended Purpose	These devices are intended for soft tissue to bone, or soft tissue repair and/or reconstruction.

Applicable Certificates	
93/42/EEC Annex II Certificate	CE 02271
Quality Management System – EN ISO 13485	MDSAP 667872
93/42/EEC Annex II, Section 4 Design Examination Certificate	N/A

Responsible Authority	
 <small>DocuSigned by Tracy Johnson</small> <small>I approve this document</small> <small>30-Mar-2021 10:02:17 EDT</small>	30-Mar-2021 10:02:25 EDT
<small>5327EBBD8E7B4CB5A09F0680473BE64F</small> Tracy Johnson, Associate Director Regulatory Affairs	Date



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Appendix 1 – Device Details

Item Number	Item Description	Classification	Classification Rule
010000324	JuggerKnot Long Single Loaded # 2 Blue/White MaxBraid	IIb	Rule 8
010000334	JuggerKnot Long Single Loaded #1 Maxbraid - Blue/White	IIb	Rule 8
010000335	JuggerKnot Long Single Loaded #2 Maxbraid - Blue	IIb	Rule 8
912000	JuggerKnot SINGLE LOADED IMPLANT SYSTEM 1.4mm 1 #1 Mabraid- Blue/White	IIb	Rule 8
912010	JuggerKnot SINGLE LOADED, 1.4mm 1 #1Maxbraid- Blue/White	IIb	Rule 8
912015	JuggerKnot SINGLE LOADED, 1.5mm 1 #2 Maxbraid- Blue/White	IIb	Rule 8
912029	JuggerKnot DOUBLE LOADED, 2.9mm 2 #2 Maxbraid- Blue, Blue/White	IIb	Rule 8
912030	JuggerKnot SINGLE LOADED, 1.4mm 1 #1 Maxbraid- Blue/White	IIb	Rule 8
912031	JuggerKnot SINGLE LOADED, 1.5mm 1 #2 Maxbraid- Blue/White	IIb	Rule 8
912050	JuggerKnot DOUBLE LOADED, 2.9mm 2 #2 Maxbraid- White, Blue/White	IIb	Rule 8
912068	JuggerKnot SHORT 1.4mm 1 #1 Maxbraid- Blue/White With Needles	IIb	Rule 8
912069	JuggerKnot SHORT 10PK 1.4mm 1 #1 Maxbraid- Blue/White With Needles	IIb	Rule 8
912075	JuggerKnot Short Implant System 1.4mm 1 #1 Maxbraid- Blue/White Includes Disposable Guide and Drill	IIb	Rule 8
912529	JuggerKnot DOUBLE LOADED, 2.9mm 2 #2 Maxbraid- Blue, Blue/White	IIb	Rule 8
916030	JuggerKnot Long Single Loaded #1 Blue/White MaxBraid	IIb	Rule 8
110005093	JuggerKnot DOUBLE LOADED, 2.9mm 2 #2 Maxbraid- Blue, Blue/White Cutting Needles- Short Inserter	IIb	Rule 8
110005096	JuggerKnot DOUBLE LOADED, 2.9mm 2 #2 Maxbraid- Blue, Blue/White Tapered Needles- Short Inserter	IIb	Rule 8
110005241	JuggerKnot DOUBLE LOADED , 2.9mm 2 #2 Maxbraid- Blue, Blue/White Cutting Needles- Short Inserter	IIb	Rule 8



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Item Number	Item Description	Classification	Classification Rule
110005242	JuggerKnot DOUBLE LOADED, 2.9mm 2 #2 Maxbraid- Blue, Blue/White Tapered Needles- Short Inserter	IIb	Rule 8
110005307	JuggerKnot SHORT RIGID SIZE 1, 1.45mm 1 #1 Maxbraid- Blue/White Contains Drill Bit	IIb	Rule 8
110005315	JuggerKnot SHORT RIGID SIZE 2, 1.45mm 1 #2 Maxbraid- Blue Contains Drill Bit	IIb	Rule 8
110005319	JuggerKnot SHORT RIGID SIZE 1, 1.45mm 1 #1 Maxbraid- Blue/White	IIb	Rule 8
110005320	JuggerKnot SHORT RIGID SIZE 2, 1.45mm 1 #2 Maxbraid- Blue	IIb	Rule 8



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Declaration of Conformity Revision History

Revision	Date	Revision History
A	19-Dec-2019	Initial release. New Technical File created for part numbers transferred from SM-JGK-003.
B	Date of current signature	<ul style="list-style-type: none"> • Updated DoC to current template TP132220 Rev. 1 • Updated EAR name and address to Biomet GSCC B.V. • Updated Revision level from A to B