

Biomet Orthopedics, Inc.  
56 East Bell Drive,  
P.O Box 587 Warsaw,  
IN 46581.

07-09-2023

**Notified Body Confirmation Letter**  
**Reference: EU2023-607/ 684419**

To whom it may concern,

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices**

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Biomet Orthopedics, Inc.  
56 East Bell Drive,  
P.O Box 587 Warsaw,  
IN 46581.

SRN Number: US-MF-000001414

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

**Ffion**  
**O'Malley**

Digitally signed by  
Ffion O'Malley  
Date: 2023.09.07  
14:06:47 +01'00'

Ffion O'Malley  
BSI Scheme Manager

**Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
"Zimmer Biomet OSS® Orthopedic Salvage System Implants (OSS Orthopedic Salvage System)"	Class III	Not Applicable	CE 512857; 12/May/2023; NB# 2797 CE 677937; 10/Feb/2024; NB# 2797
TaperLoc Hip System	Class III	Not Applicable	CE 542203; 26/Apr/2024; NB# 2797
Echo Bi-Metric Hip System Implants	Class III	Not Applicable	CE512342; 06/July/2023; NB# 2797
Comprehensive Shoulder System ('Comprehensive Anatomic Shoulder')	Class III	Not Applicable	CE 525558; 29/Jan/2024; NB# 2797
Freedom Constrained Liner System	Class III	Not Applicable	CE 532522; 30/Nov/2023; NB# 2797
Arcos Modular Revision Hip Systems	Class III	Not Applicable	CE 552505; 26/May/2024; NB#2797
Vanguard 360 Revision Knee System	Class III	Not Applicable	CE550300; 26/May/2024; NB#2797
ExploR Radial Head	Class III	Not Applicable	CE02461; 26/May/2024; NB#2797
Affixus Hip Fracture Nail System	Class IIb	Not Applicable	CE579917; 26/May/2024; NB#2797
Kirschner Wires	Class IIb	Not Applicable	CE579917; 26/May/2024; NB#2797
A.L.P.S. Large Fragment Plating System	Class IIb	Not Applicable	CE579917; 26/May/2024; NB#2797
Gentle Threads Interference Screws	Class III	Not Applicable	EU7007.III.CE02237; 28/April/2024; NB#2797
Comprehensive Shoulder System - Glenoid Screws	Class III	Not Applicable	EUMDD5018.III.CE560438; 26/May/2024; NB#2797
Comprehensive Reverse Shoulder	Class III	Not Applicable	EUMDD5018.III.CE560438; 26/May/2024; NB#2797
Comprehensive Augmented Baseplates	Class III	Not Applicable	CE560438; 26/May/2024; NB#2797

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<b>ToggleLoc with ZipLoop</b>	Class IIb	Not Applicable	CE02271; 11/March/2024 NB# 2797
<b>Titanium Interference Screws</b>	Class IIb	Not Applicable	CE02271; 11/March/2024 NB# 2797
<b>Endo BiPolar Hip</b>	Class III	Not Applicable	CE02461; 26/May/2024; NB#2797
<b>Compress® and Mini-Compress® System (Compress Segmental Accessory Implant Devices)</b>	Class III	Not Applicable	CE 677937; 10/Feb/2024; NB# 2797
<b>JuggerStitch Meniscal Repair Device Instruments</b>	Class IIa	Not Applicable	EU7022.IIa-I JuggerStitch Meniscal Repair Device Instruments CE02271; 11/March/2024 NB# 2797
<b>JuggerKnot 1_4 and 1_5 and 2_9</b>	Class IIa	Not Applicable	EU7000.IIa-I JuggerKnot Soft Anchor Instrument CE02271; 11/March/2024 NB# 2797
<b>AllThread TI</b>	Class IIa	Not Applicable	EU7003.IIb ALLThread Suture Anchor Implants CE02271; 11/March/2024 NB# 2797
<b>Titanium Interference Screws</b>	Class IIa	Not Applicable	EU7006.IIa-I Titanium Interference Screw Instrument CE02271; 11/March/2024 NB# 2797
<b>Graft Harvesting and Prep Instruments</b>	Class IIa	Not Applicable	EU7013.IIa-I General Sports Medicine Instrument CE02271; 11/March/2024 NB# 2797
<b>HydroDam</b>	Class IIa	Not Applicable	EU7020.IIa-I HydroDam Cannula System CE02271; 11/March/2024 NB# 2797
<b>Juggerknot Long System</b>	Class IIa	Not Applicable	EU7000.IIa-I JuggerKnot Soft Anchor Instruments CE02271; 11/March/2024 NB# 2797
<b>Gentle Threads™ Interference Screws</b>	Class IIa	Not Applicable	EU7007.IIa-I Gentle Threads Interference Screws Instruments CE02271; 11/March/2024 NB# 2797
<b>ToggleLoc with ZipLoop</b>	Class IIa	Not Applicable	EU7010.IIa-I Rev C ToggleLoc and ZipTight Instruments

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			CE02271; 11/March/2024 NB# 2797
<b>Ziptight</b>	Class IIa	Not Applicable	EU7010.IIa-I Rev C ToggleLoc and ZipTight Instruments CE02271; 11/March/2024 NB# 2797
<b>JuggerLoc</b>	Class IIa	Not Applicable	EU7012.IIa-I Rev. B JuggerLoc Soft Tissue Instruments CE02271; 11/March/2024 NB# 2797
<b>ACL/PCL Instruments</b>	Class IIa	Not Applicable	EU7013.IIa-I General Instruments CE02271; 11/March/2024 NB# 2797
<b>General Instruments</b>	Class IIa	Not Applicable	EU7013.IIa-I General Instruments CE02271; 11/March/2024 NB# 2797
<b>Valence Instrumentation</b>	Class IIa	Not Applicable	EU7013.IIa-I General Instruments CE02271; 11/March/2024 NB# 2797
<b>JuggerKnot Mini</b>	Class IIb - Implantable - WET	Not Applicable	EU7001.IIb JuggerKnot Mini Soft Anchor Implants CE02271; 11/March/2024 NB# 2797
<b>JuggerStitch® Meniscal Repair Device</b>	Class IIb - Implantable - WET	Not Applicable	EU7022.IIb JuggerStitch Meniscal Repair Device CE02271; 11/March/2024 NB# 2797
<b>Titanium Interference Screws Implants</b>	Class IIb - Implantable - WET	Not Applicable	EU7006.IIb Titanium Interference Screws Implants CE02271; 11/March/2024 NB# 2797
<b>JuggerKnot 1_4 and 1_5 and 2_9</b>	Class IIb - Implantable - WET	Not Applicable	EU7000.IIb JuggerKnot Soft Anchor Implants CE02271; 11/March/2024 NB# 2797
<b>AllThread TI</b>	Class IIb - Implantable - WET	Not Applicable	EU7003.IIb ALLThread Suture Anchor Implants CE02271; 11/March/2024 NB# 2797
<b>ToggleLoc with ZipLoop</b>	Class IIb - Implantable - WET	Not Applicable	EUMDD7010.IIB ToggleLoc and ZipTight Implants CE02271; 11/March/2024 NB# 2797
<b>Juggerknot Long System</b>	Class IIb - Implantable - WET	Not Applicable	EU7000.IIb JuggerKnot Soft Anchor CE02271; 11/March/2024

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<b>ExpressBraid</b>	Class IIb - Implantable - WET	Not Applicable	NB# 2797 EU7008.IIb Sports Medicine Suture Implants CE02271; 11/March/2024 NB# 2797
<b>Ziptight</b>	Class IIb - Implantable - WET	Not Applicable	EU7010.IIb ToggerLoc and ZipTight Implants CE02271; 11/March/2024 NB# 2797
<b>JuggerLoc</b>	Class IIb - Implantable - WET	Not Applicable	EU7012.IIb JuggerLoc Soft Tissue Implants CE02271; 11/March/2024 NB# 2797

**Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<b>Vanguard Knee System addition of polished tibial trays</b>	Class III	Not Applicable	2008 12 0587 ED; 19/April/2024; NB#0318

### Confirmation Letter Revision History

Date	Action
2023/09/07	Initial issue