

Innovative Design Orthopaedics,  
6 Brewery Court,  
Theale,  
Reading,  
RG7 5AJ  
UK

06/07/2023

**Notified Body Confirmation Letter**  
**Reference: EU2023-607/[ID 630000]**

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:

Innovative Design Orthopaedics,  
6 Brewery Court,  
Theale,  
Reading,  
RG7 5AJ  
UK

SRN Number: GB-MF-000026411

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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  
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
36mm, 3mm Lat, 10° Humeral Liner	Class III	36mm, 3mm Lat, 10° Humeral Liner	CE 598321
36mm, 6mm Lat, 10° Humeral Liner	Class III	36mm, 6mm Lat, 10° Humeral Liner	CE 598321
36mm, 9mm Lat, 10° Humeral Liner	Class III	36mm, 9mm Lat, 10° Humeral Liner	CE 598321
36mm, 12mm Lat, 10° Humeral Liner	Class III	36mm, 12mm Lat, 10° Humeral Liner	CE 598321
36mm, 3mm Lat, RET, 10° Humeral Liner	Class III	36mm, 3mm Lat, RET, 10° Humeral Liner	CE 598321
36mm, 6mm Lat, RET, 10° Humeral Liner	Class III	36mm, 6mm Lat, RET, 10° Humeral Liner	CE 598321
36mm, 9mm Lat, RET, 10° Humeral Liner	Class III	36mm, 9mm Lat, RET, 10° Humeral Liner	CE 598321
36mm, 12mm Lat, RET, 10° Humeral Liner	Class III	36mm, 12mm Lat, RET, 10° Humeral Liner	CE 598321
41mm, 3mm Lat, 10° Humeral Liner	Class III	41mm, 3mm Lat, 10° Humeral Liner	CE 598321
41mm, 6mm Lat, 10° Humeral Liner	Class III	41mm, 6mm Lat, 10° Humeral Liner	CE 598321
41mm, 9mm Lat, 10° Humeral Liner	Class III	41mm, 9mm Lat, 10° Humeral Liner	CE 598321
41mm, 12mm Lat, 10° Humeral Liner	Class III	41mm, 12mm Lat, 10° Humeral Liner	CE 598321
41mm, 3mm Lat, RET, 10° Humeral Liner	Class III	41mm, 3mm Lat, RET, 10° Humeral Liner	CE 598321
41mm, 6mm Lat, RET, 10° Humeral Liner	Class III	41mm, 6mm Lat, RET, 10° Humeral Liner	CE 598321
41mm, 9mm Lat, RET, 10° Humeral Liner	Class III	41mm, 9mm Lat, RET, 10° Humeral Liner	CE 598321

<b>Device name or Basic UDI-DI (under MDR application)</b>	<b>MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)</b>	<b>If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device</b>	<b>MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification</b>
41mm, 12mm Lat, RET, 10° Humeral Liner	Class III	41mm, 12mm Lat, RET, 10° Humeral Liner	CE 598321
36mm Dia Glenoid Head	Class III	36mm Dia Glenoid Head	CE 598321
41mm Dia Glenoid Head	Class III	41mm Dia Glenoid Head	CE 598321
Glenoid Baseplate	Class III	Glenoid Baseplate	CE 598321
Long Glenoid Baseplate	Class III	Long Glenoid Baseplate	CE 598321
Small Humeral Shell	Class III	Small Humeral Shell	CE 598321
Medium Humeral Shell	Class III	Medium Humeral Shell	CE 598321
Large Humeral Shell	Class III	Large Humeral Shell	CE 598321
X-Large Humeral Shell	Class III	X-Large Humeral Shell	CE 598321
Locking Ring	Class III	Locking Ring	CE 598321
Small Stemmed Humeral Shell	Class III	Small Stemmed Humeral Shell	CE 598321
Medium Stemmed Humeral Shell	Class III	Medium Stemmed Humeral Shell	CE 598321
Large Stemmed Humeral Shell	Class III	Large Stemmed Humeral Shell	CE 598321
X-Large Stemmed Humeral Shell	Class III	X-Large Stemmed Humeral Shell	CE 598321
Humeral Hemi Head 50mmx0mm	Class III	Humeral Hemi Head 50mmx0mm	CE 598321
Humeral Mega Head 50mmx8mm	Class III	Humeral Mega Head 50mmx8mm	CE 598321
Titanium Screw Low Profile 5x15mm	Class III	Titanium Screw Low Profile 5x15mm	CE 598321
Titanium Screw Low Profile 5x20mm	Class III	Titanium Screw Low Profile 5x20mm	CE 598321
Titanium Screw Low Profile 5x25mm	Class III	Titanium Screw Low Profile 5x25mm	CE 598321
Titanium Screw Low Profile 5x30mm	Class III	Titanium Screw Low Profile 5x30mm	CE 598321
Titanium Screw Low Profile 5x35mm	Class III	Titanium Screw Low Profile 5x35mm	CE 598321

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Titanium Screw Low Profile 5x40mm	Class III	Titanium Screw Low Profile 5x40mm	CE 598321
Titanium Screw Low Profile 5x45mm	Class III	Titanium Screw Low Profile 5x45mm	CE 598321
Titanium Screw Low Profile 5x50mm	Class III	Titanium Screw Low Profile 5x50mm	CE 598321
402812 - VERSO TRIAL LINER 36MM X 3MM LATERAL,10 DEG	Class IIa	402812 - VERSO TRIAL LINER 36MM X 3MM LATERAL,10 DEG	CE 598321
402813 - VERSO TRIAL LINER 36MM X 6MM LATERAL,10 DEG	Class IIa	402813 - VERSO TRIAL LINER 36MM X 6MM LATERAL,10 DEG	CE 598321
402814 - VERSO TRIAL LINER 36MM X 9MM LATERAL,10 DEG	Class IIa	402814 - VERSO TRIAL LINER 36MM X 9MM LATERAL,10 DEG	CE 598321
402815 - VERSO TRIAL LINER 36MM X 12MM LATERAL,10 DEG	Class IIa	402815 - VERSO TRIAL LINER 36MM X 12MM LATERAL,10 DEG	CE 598321
402817 - VERSO TRIAL LINER 36MM X 3MM LATERAL, RETENTIVE 10 DEG	Class IIa	402817 - VERSO TRIAL LINER 36MM X 3MM LATERAL, RETENTIVE 10 DEG	CE 598321
402818 - VERSO TRIAL LINER 36MM X 6MM LATERAL, RETENTIVE 10 DEG	Class IIa	402818 - VERSO TRIAL LINER 36MM X 6MM LATERAL, RETENTIVE 10 DEG	CE 598321
402819 - VERSO TRIAL LINER 36MM X 9MM LATERAL, RETENTIVE 10 DEG	Class IIa	402819 - VERSO TRIAL LINER 36MM X 9MM LATERAL, RETENTIVE 10 DEG	CE 598321
402820 - VERSO TRIAL LINER 36MM X 12MM LATERAL, RETENTIVE 10 DEG	Class IIa	402820 - VERSO TRIAL LINER 36MM X 12MM LATERAL, RETENTIVE 10 DEG	CE 598321
402822 - VERSO TRIAL LINER 41MM X 3MM LATERAL,10 DEG	Class IIa	402822 - VERSO TRIAL LINER 41MM X 3MM LATERAL,10 DEG	CE 598321

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402823 - VERSO TRIAL LINER 41MM X 6MM LATERAL,10 DEG		402823 - VERSO TRIAL LINER 41MM X 6MM LATERAL,10 DEG	CE 598321
402824 - VERSO TRIAL LINER 41MM X 9MM LATERAL,10 DEG	Class IIa	402824 - VERSO TRIAL LINER 41MM X 9MM LATERAL,10 DEG	CE 598321
402825 - VERSO TRIAL LINER 41MM X 12MM LATERAL,10 DEG	Class IIa	402825 - VERSO TRIAL LINER 41MM X 12MM LATERAL,10 DEG	CE 598321
402827 - VERSO TRIAL LINER 41MM X 3MM LATERAL, RETENTIVE 10 DEG	Class IIa	402827 - VERSO TRIAL LINER 41MM X 3MM LATERAL, RETENTIVE 10 DEG	CE 598321
402828 - VERSO TRIAL LINER 41MM X 6MM LATERAL, RETENTIVE 10 DEG	Class IIa	402828 - VERSO TRIAL LINER 41MM X 6MM LATERAL, RETENTIVE 10 DEG	CE 598321
402829 - VERSO TRIAL LINER 41MM X 9MM LATERAL, RETENTIVE 10 DEG	Class IIa	402829 - VERSO TRIAL LINER 41MM X 9MM LATERAL, RETENTIVE 10 DEG	CE 598321
402830 - VERSO TRIAL LINER 41MM X 12MM LATERAL, RETENTIVE 10 DEG	Class IIa	402830 - VERSO TRIAL LINER 41MM X 12MM LATERAL, RETENTIVE 10 DEG	CE 598321
402812 - VERSO TRIAL LINER 36MM X 3MM LATERAL,10 DEG	Class IIa	402812 - VERSO TRIAL LINER 36MM X 3MM LATERAL,10 DEG	CE 598321
402879 - VERSO SHOULDER PROXIMAL HUMERAL REAMER	Class IIa	402879 - VERSO SHOULDER PROXIMAL HUMERAL REAMER	CE 598321
402869 - VERSO TRIAL HUMERAL HEMI HEAD 50MM X 0MM	Class IIa	402869 - VERSO TRIAL HUMERAL HEMI HEAD 50MM X 0MM	CE 598321
402869 - VERSO TRIAL HUMERAL HEMI HEAD 50MM X 0MM	Class IIa	402869 - VERSO TRIAL HUMERAL HEMI HEAD 50MM X 0MM	CE 598321



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402834 - VERSO SHOULDER 5MM STOP DRILL BIT	Class IIa	402834 - VERSO SHOULDER 5MM STOP DRILL BIT	CE 598317
402430 - VERSO SHOULDER GLENIOD FACE REAMER	Class IIa	402430 - VERSO SHOULDER GLENIOD FACE REAMER	CE 598317
402838 - VERSO GLENOID STEP REMOVAL REAMER	Class IIa	402838 - VERSO GLENOID STEP REMOVAL REAMER	CE 598317
402839 - VERSO GLENOID PEG REAMER	Class IIa	402839 - VERSO GLENOID PEG REAMER	CE 598317
402847 - VERSO GLENOID DRILL BIT 3.0 MM X 225MM	Class IIa	402847 - VERSO GLENOID DRILL BIT 3.0 MM X 225MM	CE 598317
402868 - VERSO GLENOID DRILL BIT 3.5 MM X 225MM	Class IIa	402868 - VERSO GLENOID DRILL BIT 3.5 MM X 225MM	CE 598317
402873 - VERSO TRIAL GLENOID HEAD 36MM	Class IIa	402873 - VERSO TRIAL GLENOID HEAD 36MM	CE 598321
402874 - VERSO TRIAL GLENOID HEAD 41MM	Class IIa	402874 - VERSO TRIAL GLENOID HEAD 41MM	CE 598321
402835 - Verso Cannulated 5mm stop drill bit	Class IIa	402835 - Verso Cannulated 5mm stop drill bit	CE 598317

### Confirmation Letter Revision History

Date	Action
2023/07/06	Initial issue