By Royal Charter

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 598321**

Issued To: **Innovative Design Orthopaedics Limited**
6 Brewery Court
Theale
Reading
Berkshire
RG7 5AJ
United Kingdom

In respect of:

Verso Shoulder System

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4 and Commission Directive 2005/50/EC. The design conforms to the requirements of 93/42/EEC. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2013-10-11** Date: **2021-04-15** Expiry Date: **2023-10-10**

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
124512	Humeral Liner	36mm, 3mm Lat, 10°	Verso total shoulder arthroplasty	III
124513	Humeral Liner	36mm, 6mm Lat, 10°		
124514	Humeral Liner	36mm, 9mm Lat, 10°		
124515	Humeral Liner	36mm, 12mm Lat, 10°		
124517	Humeral Liner	36mm, 3mm Lat, RET, 10°		
124518	Humeral Liner	36mm, 6mm Lat, RET, 10°		
124519	Humeral Liner	36mm, 9mm Lat, RET, 10°		
124520	Humeral Liner	36mm, 12mm Lat, RET, 10°		
124522	Humeral Liner	41mm, 3mm Lat, 10°		
124523	Humeral Liner	41mm, 6mm Lat, 10°		
124524	Humeral Liner	41mm, 9mm Lat, 10°		
124525	Humeral Liner	41mm, 12mm Lat, 10°		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
124527	Humeral Liner	41mm, 3mm Lat, RET, 10°	Verso total shoulder arthroplasty	III
124528	Humeral Liner	41mm, 6mm Lat, RET, 10°		
124529	Humeral Liner	41mm, 9mm Lat, RET, 10°		
124530	Humeral Liner	41mm, 12mm Lat, RET, 10°		
124573	Glenoid Head	36mm Dia		
124574	Glenoid Head	41mm Dia		
124572	Glenoid Baseplate	Standard		
124576	Glenoid Baseplate	Long		
124564	Humeral Shell	Small		
124565	Humeral Shell	Medium		
124566	Humeral Shell	Large		
124567	X-Large	Humeral Shell		
105444-3	Locking Ring			

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
124560	Stemmed Humeral Shell	Small	Verso total shoulder arthroplasty	III
124561	Stemmed Humeral Shell	Medium		
124562	Stemmed Humeral Shell	Large		
124563	Stemmed Humeral Shell	X-Large		
113843	Titanium Screw Low Profile	5x15mm		
113844	Titanium Screw Low Profile	5x20mm		
113845	Titanium Screw Low Profile	5x25mm		
113846	Titanium Screw Low Profile	5x30mm		
113847	Titanium Screw Low Profile	5x35mm		

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
113848	Titanium Screw Low Profile	5x40mm	Verso total shoulder arthroplasty	III
113861	Titanium Screw Low Profile	5x45mm		
113862	Titanium Screw Low Profile	5x50mm		

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Certificate History

Date	Reference Number	Action
11 October 2013	10142589	First issue.
09 October 2018	8940322	Certificate renewal.
18 February 2019	9719586	Traceable to NB 0086.
17 March 2021	3369181	Change of address of Legal Manufacturer from "64 Baker Street, London" to "6 Brewery Court, Reading"
Current	3053750	Addition of "124576 Glenoid Baseplate-Long" Approval of single rework process for HA coating for part numbers 124572, 124576, 124560-124567

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