

DECLARATION of CONFORMITY – DoC

We the Manufacturer:

Biomet UK Ltd
Waterton Industrial Estate
Bridgend
CF31 3XA

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Declaration:

The devices specified below fulfil the obligations of MDD 93/42/EC and meet the relevant Essential Requirements listed in annex I of the aforementioned directive.

Product Group:

Knee System

Product Family:

Oxford Fixed Lateral Knee System

Product Schedule:

Part number listing below


Classification:

Class III

Per Council Directive 2005/50/EC concerning medical devices (MDD) and council directive 93/42/EEC concerning medical devices – (MDD)

Date of First CE mark:

First issue DoC: The devices were first placed on the market on the date shown below.

Directives:	Council Directive 93/42/EEC concerning medical devices, i.e., Medical Device Directive – MDD and council Directive 2005/50/EC	
	Annex I Essential Requirements	
	Annex II EC Declaration of Conformity Full QAS –	
Registrations: Certifications:	Certificate No.	Type
	CE 00520	EC Certificate –Full Quality Assurance
	CE 511079	Design Examination Certificate
Notified Body:	Notified Body:	Notified Body No:
	BSI Product Services	0086
	Kitemark Court	
	Davy Avenue, Knowlhill	
	Milton Keynes MK5 8PP	
	United Kingdom	
Biomet Responsible Authority	Signature: 	Date: 10 NOV 2014
	Natalie Wide—Director of Regulatory Compliance and QA	

NB All implants are class III according to path 1 (see Appendix 2)

Part No	Description	GMDN
154320	OXFORD FIXED LATERAL BEARING A3 LEFT	34195
154321	OXFORD FIXED LATERAL BEARING A4 LEFT	34195
154322	OXFORD FIXED LATERAL BEARING A5 LEFT	34195
154323	OXFORD FIXED LATERAL BEARING A6 LEFT	34195
154324	OXFORD FIXED LATERAL BEARING A7 LEFT	34195
154325	OXFORD FIXED LATERAL BEARING B3 LEFT	34195
154326	OXFORD FIXED LATERAL BEARING B4 LEFT	34195
154327	OXFORD FIXED LATERAL BEARING B5 LEFT	34195
154328	OXFORD FIXED LATERAL BEARING B6 LEFT	34195
154329	OXFORD FIXED LATERAL BEARING B7 LEFT	34195
154330	OXFORD FIXED LATERAL BEARING C3 LEFT	34195
154331	OXFORD FIXED LATERAL BEARING C4 LEFT	34195
154332	OXFORD FIXED LATERAL BEARING C5 LEFT	34195
154333	OXFORD FIXED LATERAL BEARING C6 LEFT	34195
154334	OXFORD FIXED LATERAL BEARING C7 LEFT	34195
154335	OXFORD FIXED LATERAL BEARING D3 LEFT	34195
154336	OXFORD FIXED LATERAL BEARING D4 LEFT	34195
154337	OXFORD FIXED LATERAL BEARING D5 LEFT	34195
154338	OXFORD FIXED LATERAL BEARING D6 LEFT	34195
154339	OXFORD FIXED LATERAL BEARING D7 LEFT	34195
154340	OXFORD FIXED LATERAL BEARING E3 LEFT	34195
154341	OXFORD FIXED LATERAL BEARING E4 LEFT	34195
154342	OXFORD FIXED LATERAL BEARING E5 LEFT	34195
154343	OXFORD FIXED LATERAL BEARING E6 LEFT	34195
154344	OXFORD FIXED LATERAL BEARING E7 LEFT	34195
154345	OXFORD FIXED LATERAL BEARING F3 LEFT	34195
154346	OXFORD FIXED LATERAL BEARING F4 LEFT	34195
154347	OXFORD FIXED LATERAL BEARING F5 LEFT	34195
154348	OXFORD FIXED LATERAL BEARING F6 LEFT	34195
154349	OXFORD FIXED LATERAL BEARING F7 LEFT	34195
154350	OXFORD FIXED LATERAL BEARING A3 RIGHT	34195
154351	OXFORD FIXED LATERAL BEARING A4 RIGHT	34195
154352	OXFORD FIXED LATERAL BEARING A5 RIGHT	34195
154353	OXFORD FIXED LATERAL BEARING A6 RIGHT	34195
154354	OXFORD FIXED LATERAL BEARING A7 RIGHT	34195
154355	OXFORD FIXED LATERAL BEARING B3 RIGHT	34195
154356	OXFORD FIXED LATERAL BEARING B4 RIGHT	34195
154357	OXFORD FIXED LATERAL BEARING B5 RIGHT	34195
154358	OXFORD FIXED LATERAL BEARING B6 RIGHT	34195
154359	OXFORD FIXED LATERAL BEARING B7 RIGHT	34195
154360	OXFORD FIXED LATERAL BEARING C3 RIGHT	34195

Part No	Description	GMDN
154361	OXFORD FIXED LATERAL BEARING C4 RIGHT	34195
154362	OXFORD FIXED LATERAL BEARING C5 RIGHT	34195
154363	OXFORD FIXED LATERAL BEARING C6 RIGHT	34195
154364	OXFORD FIXED LATERAL BEARING C7 RIGHT	34195
154365	OXFORD FIXED LATERAL BEARING D3 RIGHT	34195
154366	OXFORD FIXED LATERAL BEARING D4 RIGHT	34195
154367	OXFORD FIXED LATERAL BEARING D5 RIGHT	34195
154368	OXFORD FIXED LATERAL BEARING D6 RIGHT	34195
154369	OXFORD FIXED LATERAL BEARING D7 RIGHT	34195
154370	OXFORD FIXED LATERAL BEARING E3 RIGHT	34195
154371	OXFORD FIXED LATERAL BEARING E4 RIGHT	34195
154372	OXFORD FIXED LATERAL BEARING E5 RIGHT	34195
154373	OXFORD FIXED LATERAL BEARING E6 RIGHT	34195
154374	OXFORD FIXED LATERAL BEARING E7 RIGHT	34195
154375	OXFORD FIXED LATERAL BEARING F3 RIGHT	34195
154376	OXFORD FIXED LATERAL BEARING F4 RIGHT	34195
154377	OXFORD FIXED LATERAL BEARING F5 RIGHT	34195
154378	OXFORD FIXED LATERAL BEARING F6 RIGHT	34195
154379	OXFORD FIXED LATERAL BEARING F7 RIGHT	34195