



UK LIMITED

Product Group: Knee Implant System – Class III

Rev. 7

Technical File No. A025

Date Prepared: 09/05/2013

**DECLARATION of CONFORMITY – DoC****We the Manufacturer:**

Biomet UK Ltd  
Waterton Industrial Estate  
Bridgend  
CF31 3XA

☎ 44-1656-655221    📠 44-1656-645454

**Declaration:**

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

**Product Group:**

Knee System

**Product Family:**

Oxford Domed Lateral Knee System

**Product Schedule:**

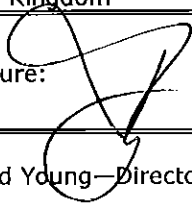
Part number listing below

**Classification:****Class III**

Per Council Directive 2005/50/EC concerning medical devices (MDD) & Council Directive 93/42/EEC concerning medical devices (MDD)

**Date of First CE mark:**

The devices were first placed on the market on 10/10/2006

<b>Directives:</b>	<i>Council Directive 93/42/EEC concerning medical devices, i.e., Medical Device Directive – MDD &amp; Council Directive 2005/50/EC concerning medical devices</i>	
	Annex I Essential Requirements	
	Annex II EC Declaration of Conformity Full QAS –	
<b>Registrations: Certifications:</b>	<b>Certificate No.</b>	<b>Type</b>
	CE 00520	EC Certificate –Full Quality Assurance
	FM 71429	Certificate of registration –QMS
	CE 511079	EC Design Examination Certificate
<b>Notified Body:</b>	<b>Notified Body:</b>	<b>Notified Body No:</b>
	BSI Product Services	0086
	Kitemark Court	
	Davy Avenue, Knowlhill	
	Milton Keynes MK5 8PP	
	United Kingdom	
<b>Biomet Responsible Authority</b>	Signature: 	Date: 10 May 2013
	Richard Young—Director of Regulatory Compliance and QA	

PROPRIETARY &amp; CONFIDENTIAL

BIOMET@UK LIMITED

NOTE: MASTER maintained electronically within the Regulatory Department, printed and unsigned document is an UNCONTROLLED COPY.

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

CAT NO.	DESCRIPTION	EU Class	GMDN
166551	Domed Lateral Cemented Tibial Size A	III	34195
166552	Domed Lateral Cemented Tibial Size B	III	34195
166553	Domed Lateral Cemented Tibial Size C	III	34195
166554	Domed Lateral Cemented Tibial Size D	III	34195

“ARCOM” MOULDED MENISCAL			
CAT NO.	DESCRIPTION	EU Class	GMDN
161680	Domed Lateral Bearings Extra Small Size 3	III	34195
161681	Domed Lateral Bearings Extra Small Size 4	III	34195
161682	Domed Lateral Bearings Extra Small Size 5	III	34195
161683	Domed Lateral Bearings Extra Small Size 6	III	34195
161684	Domed Lateral Bearings Extra Small Size 7	III	34195
161685	Domed Lateral Bearings Extra Small Size 8	III	34195
161686	Domed Lateral Bearings Extra Small Size 9	III	34195
161687	Domed Lateral Bearings Small Size 3	III	34195
161688	Domed Lateral Bearings Small Size 4	III	34195
161689	Domed Lateral Bearings Small Size 5	III	34195
161690	Domed Lateral Bearings Small Size 6	III	34195
161691	Domed Lateral Bearings Small Size 7	III	34195
161692	Domed Lateral Bearings Small Size 8	III	34195
161693	Domed Lateral Bearings Small Size 9	III	34195
161694	Domed Lateral Bearings Medium Size 3	III	34195
161695	Domed Lateral Bearings Medium Size 4	III	34195
161696	Domed Lateral Bearings Medium Size 5	III	34195
161697	Domed Lateral Bearings Medium Size 6	III	34195
161698	Domed Lateral Bearings Medium Size 7	III	34195
161699	Domed Lateral Bearings Medium Size 8	III	34195
161700	Domed Lateral Bearings Medium Size 9	III	34195
161701	Domed Lateral Bearings Large Size 3	III	34195
161702	Domed Lateral Bearings Large Size 4	III	34195
161703	Domed Lateral Bearings Large Size 5	III	34195
161704	Domed Lateral Bearings Large Size 6	III	34195
161705	Domed Lateral Bearings Large Size 7	III	34195
161706	Domed Lateral Bearings Large Size 8	III	34195
161707	Domed Lateral Bearings Large Size 9	III	34195