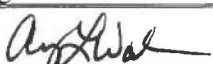


Technical File – Declaration of Conformity

Technical File: KN-360-004

We the Manufacturer:	Authorized European Community Representative and Location of Responsible Person:
Biomet Orthopedics P.O. Box 587 56 East Bell Drive Warsaw, Indiana 46581 USA ☎800-348-9500	Biomet U.K. Limited Waterton Industrial Estate South Wales Bridgend CF 31 3XA United Kingdom ☎44-1656-655221 📠 44-1656-645454

Declaration:	We hereby declare under our sole responsibility that the following products meet the classification, requirements, relevant directive provisions, harmonized standards, normative documents, registrations and certifications referenced below and within the technical file referenced above.
Product Group:	Knee / Sterile Accessory Implantable Devices
Product Family:	Vanguard™ 360 Revision Knee Accessory Implant Devices
Product Schedule:	Part number listing below
Classification:	Class IIb: Refer to part number listing below

Directives:	Council Directive 93/42/EEC and subsequent amendments concerning medical devices, i.e, Medical Device Directive – MDD:	
	Annex I Essential Requirements	
	Annex II EC Declaration of Conformity Full QAS – (Section 4 exception)	
Registrations and Certifications:	Certificate No.	Type
	CE 02461	EC Certificate – Full Quality Assurance
	FM 71264	CMDCAS Certificate
Notified Body:	Notified Body:	Notified Body No.:
	BSI Product Services Kitemark Court Davy Avenue, Knowlhill Milton Keynes, MK5 8PP United Kingdom	0086
Biomet Responsible Authority	Signature: 	Date: 18 - SEPT-2015
	Amy Walriven, Associate Director Regulatory Affairs	

Technical File – Declaration of Conformity

Catalog / Product No.	Description	Sterile / Non-sterile	Reusable? Yes or No	Classification	Classification Rule Number per Annex IX	GMDN Code
185210	Biomet® 360 Offset Adapter 2.5mm	Sterile	No	I Ib	8	32832
185211	Biomet® 360 Offset Adapter 5.0mm	Sterile	No	I Ib	8	32832
185212	Biomet® 360 Offset Adapter 7.5mm	Sterile	No	I Ib	8	32832
185213	Biomet® 360 Taper Screw	Sterile	No	I Ib	8	32854
185214	Biomet® 360 Tibial Small Cruciate Wing	Sterile	No	I Ib	8	48067
185215	Biomet® 360 Tibial Large Cruciate Wing	Sterile	No	I Ib	8	48067
185216-00	Biomet 360 8-32 Set Screw	Sterile	No	I Ib	8	32854
185220	Biomet® 360 Tibial Augment 59x5mm	Sterile	No	I Ib	8	48067
185221	Biomet® 360 Tibial Augment 63x5mm	Sterile	No	I Ib	8	48067
185222	Biomet® 360 Tibial Augment 67x5mm	Sterile	No	I Ib	8	48067
185223	Biomet® 360 Tibial Augment 71x5mm	Sterile	No	I Ib	8	48067
185224	Biomet® 360 Tibial Augment 75x5mm	Sterile	No	I Ib	8	48067
185225	Biomet® 360 Tibial Augment 79x5mm	Sterile	No	I Ib	8	48067
185226	Biomet® 360 Tibial Augment 83x5mm	Sterile	No	I Ib	8	48067
185227	Biomet® 360 Tibial Augment 87x5mm	Sterile	No	I Ib	8	48067
185228	Biomet® 360 Tibial Augment 91x5mm	Sterile	No	I Ib	8	48067
185229	Biomet® 360 Tibial Augment Bolt 5mm	Sterile	No	I Ib	8	48067
185230	Biomet® 360 Tibial Augment 59x10mm	Sterile	No	I Ib	8	48067
185231	Biomet® 360 Tibial Augment 63x10mm	Sterile	No	I Ib	8	48067
185232	Biomet® 360 Tibial Augment 67x10mm	Sterile	No	I Ib	8	48067
185233	Biomet® 360 Tibial Augment 71x10mm	Sterile	No	I Ib	8	48067
185234	Biomet® 360 Tibial Augment 75x10mm	Sterile	No	I Ib	8	48067
185235	Biomet® 360 Tibial Augment 79x10mm	Sterile	No	I Ib	8	48067
185236	Biomet® 360 Tibial Augment 83x10mm	Sterile	No	I Ib	8	48067
185237	Biomet® 360 Tibial Augment 87x10mm	Sterile	No	I Ib	8	48067
185238	Biomet® 360 Tibial Augment 91x10mm	Sterile	No	I Ib	8	48067
185239	Biomet® 360 Tibial Augment Bolt 10mm	Sterile	No	I Ib	8	48067
185240	Biomet® 360 Tibial Augment 59x15mm RL/LM	Sterile	No	I Ib	8	48067

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Catalog / Product No.	Description	Sterile / Non-sterile	Reusable? Yes or No	Classification	Classification Rule Number per Annex IX	GMDN Code
185241	Biomet® 360 Tibial Augment 63x15mm RL/LM	Sterile	No	Iib	8	48067
185242	Biomet® 360 Tibial Augment 67x15mm RL/LM	Sterile	No	Iib	8	48067
185243	Biomet® 360 Tibial Augment 71x15mm RL/LM	Sterile	No	Iib	8	48067
185244	Biomet® 360 Tibial Augment 75x15mm RL/LM	Sterile	No	Iib	8	48067
185245	Biomet® 360 Tibial Augment 79x15mm RL/LM	Sterile	No	Iib	8	48067
185246	Biomet® 360 Tibial Augment 83x15mm RL/LM	Sterile	No	Iib	8	48067
185247	Biomet® 360 Tibial Augment 87x15mm RL/LM	Sterile	No	Iib	8	48067
185248	Biomet® 360 Tibial Augment 91x15mm RL/LM	Sterile	No	Iib	8	48067
185250	Biomet® 360 Tibial Augment 59x15mm LL/RM	Sterile	No	Iib	8	48067
185251	Biomet® 360 Tibial Augment 63x15mm LL/RM	Sterile	No	Iib	8	48067
185252	Biomet® 360 Tibial Augment 67x15mm LL/RM	Sterile	No	Iib	8	48067
185253	Biomet® 360 Tibial Augment 71x15mm LL/RM	Sterile	No	Iib	8	48067
185254	Biomet® 360 Tibial Augment 75x15mm LL/RM	Sterile	No	Iib	8	48067
185255	Biomet® 360 Tibial Augment 79x15mm LL/RM	Sterile	No	Iib	8	48067
185256	Biomet® 360 Tibial Augment 83x15mm LL/RM	Sterile	No	Iib	8	48067
185257	Biomet® 360 Tibial Augment 87x15mm LL/RM	Sterile	No	Iib	8	48067
185258	Biomet® 360 Tibial Augment 91x15mm LL/RM	Sterile	No	Iib	8	48067
185300	Vanguard™ 360 Distal Femoral Augment Block 55x5 RL/LM	Sterile	No	Iib	8	48067
185301	Vanguard™ 360 Distal Femoral Augment Block 57.5x5 RL/LM	Sterile	No	Iib	8	48067
185302	Vanguard™ 360 Distal Femoral Augment Block 60x5 RL/LM	Sterile	No	Iib	8	48067
185303	Vanguard™ 360 Distal Femoral Augment Block 62.5x5 RL/LM	Sterile	No	Iib	8	48067
185304	Vanguard™ 360 Distal Femoral Augment Block 65x5 RL/LM	Sterile	No	Iib	8	48067
185305	Vanguard™ 360 Distal Femoral Augment Block 67.5x5 RL/LM	Sterile	No	Iib	8	48067
185306	Vanguard™ 360 Distal Femoral Augment Block 70x5 RL/LM	Sterile	No	Iib	8	48067
185307	Vanguard™ 360 Distal Femoral Augment Block 72.5 RL/LM	Sterile	No	Iib	8	48067
185308	Vanguard™ 360 Distal Femoral Augment Block 75x5 RL/LM	Sterile	No	Iib	8	48067
185310	Vanguard™ 360 Distal Femoral Augment Block 80x5 RL/LM	Sterile	No	Iib	8	48067
185320	Vanguard™ 360 Distal Femoral Augment Block 55x5 LL/RM	Sterile	No	Iib	8	48067

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Catalog / Product No.	Description	Sterile / Non-sterile	Reusable? Yes or No	Classification	Classification Rule Number per Annex IX	GMDN Code
185321	Vanguard™ 360 Distal Femoral Augment Block 57.5x5 LL/RM	Sterile	No	Iib	8	48067
185322	Vanguard™ 360 Distal Femoral Augment Block 60x5 LL/RM	Sterile	No	Iib	8	48067
185323	Vanguard™ 360 Distal Femoral Augment Block 62.5x5 LL/RM	Sterile	No	Iib	8	48067
185324	Vanguard™ 360 Distal Femoral Augment Block 65x5 LL/RM	Sterile	No	Iib	8	48067
185325	Vanguard™ 360 Distal Femoral Augment Block 67.5x5 LL/RM	Sterile	No	Iib	8	48067
185326	Vanguard™ 360 Distal Femoral Augment Block 70x5 LL/RM	Sterile	No	Iib	8	48067
185327	Vanguard™ 360 Distal Femoral Augment Block 72.5 LL/LM	Sterile	No	Iib	8	48067
185328	Vanguard™ 360 Distal Femoral Augment Block 75x5 LL/RM	Sterile	No	Iib	8	48067
185330	Vanguard™ 360 Distal Femoral Augment Block 80x5 LL/RM	Sterile	No	Iib	8	48067
185340	Vanguard™ 360 Universal Posterior Femoral Augment Block 55x5	Sterile	No	Iib	8	48067
185341	Vanguard™ 360 Universal Posterior Femoral Augment Block 57.5x5	Sterile	No	Iib	8	48067
185342	Vanguard™ 360 Universal Posterior Femoral Augment Block 60x5	Sterile	No	Iib	8	48067
185343	Vanguard™ 360 Universal Posterior Femoral Augment Block 62.5x5	Sterile	No	Iib	8	48067
185344	Vanguard™ 360 Universal Posterior Femoral Augment Block 65x5	Sterile	No	Iib	8	48067
185345	Vanguard™ 360 Universal Posterior Femoral Augment Block 67.5x5	Sterile	No	Iib	8	48067
185346	Vanguard™ 360 Universal Posterior Femoral Augment Block 70x5	Sterile	No	Iib	8	48067
185347	Vanguard™ 360 Universal Posterior Femoral Augment Block 72.5x5	Sterile	No	Iib	8	48067
185348	Vanguard™ 360 Universal Posterior Femoral Augment Block 75x5	Sterile	No	Iib	8	48067
185350	Vanguard™ 360 Universal Posterior Femoral Augment Block 80x5	Sterile	No	Iib	8	48067
185380	Vanguard™ 360 Distal Femoral Augment Block 55x10 RL/LM	Sterile	No	Iib	8	48067
185381	Vanguard™ 360 Distal Femoral Augment Block 57.5x10 RL/LM	Sterile	No	Iib	8	48067
185382	Vanguard™ 360 Distal Femoral Augment Block 60x10 RL/LM	Sterile	No	Iib	8	48067
185383	Vanguard™ 360 Distal Femoral Augment Block 62.5x10 RL/LM	Sterile	No	Iib	8	48067
185384	Vanguard™ 360 Distal Femoral Augment Block 65x10 RL/LM	Sterile	No	Iib	8	48067
185385	Vanguard™ 360 Distal Femoral Augment Block 67.5x10 RL/LM	Sterile	No	Iib	8	48067
185386	Vanguard™ 360 Distal Femoral Augment Block 70x10 RL/LM	Sterile	No	Iib	8	48067
185387	Vanguard™ 360 Distal Femoral Augment Block 72.5x10 RL/LM	Sterile	No	Iib	8	48067
185388	Vanguard™ 360 Distal Femoral Augment Block 75x10 RL/LM	Sterile	No	Iib	8	48067

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Catalog / Product No.	Description	Sterile / Non-sterile	Reusable? Yes or No	Classification	Classification Rule Number per Annex IX	GMDN Code
185390	Vanguard™ 360 Distal Femoral Augment Block 80x10 RL/LM	Sterile	No	Iib	8	48067
185400	Vanguard™ 360 Distal Femoral Augment Block 55x10 LL/RM	Sterile	No	Iib	8	48067
185401	Vanguard™ 360 Distal Femoral Augment Block 57.5x10 LL/RM	Sterile	No	Iib	8	48067
185402	Vanguard™ 360 Distal Femoral Augment Block 60x10 LL/RM	Sterile	No	Iib	8	48067
185403	Vanguard™ 360 Distal Femoral Augment Block 62.5x10 LL/RM	Sterile	No	Iib	8	48067
185404	Vanguard™ 360 Distal Femoral Augment Block 65x10 LL/RM	Sterile	No	Iib	8	48067
185405	Vanguard™ 360 Distal Femoral Augment Block 67.5x10 LL/RM	Sterile	No	Iib	8	48067
185406	Vanguard™ 360 Distal Femoral Augment Block 70x10 LL/RM	Sterile	No	Iib	8	48067
185407	Vanguard™ 360 Distal Femoral Augment Block 72.5x10 LL/RM	Sterile	No	Iib	8	48067
185408	Vanguard™ 360 Distal Femoral Augment Block 75x10 LL/RM	Sterile	No	Iib	8	48067
185410	Vanguard™ 360 Distal Femoral Augment Block 80x10 LL/RM	Sterile	No	Iib	8	48067
185420	Vanguard™ 360 Universal Posterior Femoral Augment Block 55x10	Sterile	No	Iib	8	48067
185421	Vanguard™ 360 Universal Posterior Femoral Augment Block 57.5x10	Sterile	No	Iib	8	48067
185422	Vanguard™ 360 Universal Posterior Femoral Augment Block 60x10	Sterile	No	Iib	8	48067
185423	Vanguard™ 360 Universal Posterior Femoral Augment Block 62.5x10	Sterile	No	Iib	8	48067
185424	Vanguard™ 360 Universal Posterior Femoral Augment Block 65x10	Sterile	No	Iib	8	48067
185425	Vanguard™ 360 Universal Posterior Femoral Augment Block 67.5x10	Sterile	No	Iib	8	48067
185426	Vanguard™ 360 Universal Posterior Femoral Augment Block 70x10	Sterile	No	Iib	8	48067
185427	Vanguard™ 360 Universal Posterior Femoral Augment Block 72.5x10	Sterile	No	Iib	8	48067
185428	Vanguard™ 360 Universal Posterior Femoral Augment Block 75x10	Sterile	No	Iib	8	48067
185430	Vanguard™ 360 Universal Posterior Femoral Augment Block 80x10	Sterile	No	Iib	8	48067
185460	Vanguard™ 360 Distal Femoral Augment Block 55x15 RL/LM	Sterile	No	Iib	8	48067
185461	Vanguard™ 360 Distal Femoral Augment Block 57.5x15 RL/LM	Sterile	No	Iib	8	48067
185462	Vanguard™ 360 Distal Femoral Augment Block 60x15 RL/LM	Sterile	No	Iib	8	48067
185463	Vanguard™ 360 Distal Femoral Augment Block 62.5x15 RL/LM	Sterile	No	Iib	8	48067
185464	Vanguard™ 360 Distal Femoral Augment Block 65x15 RL/LM	Sterile	No	Iib	8	48067
185465	Vanguard™ 360 Distal Femoral Augment Block 67.5x15 RL/LM	Sterile	No	Iib	8	48067
185466	Vanguard™ 360 Distal Femoral Augment Block 70x15 RL/LM	Sterile	No	Iib	8	48067

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Catalog / Product No.	Description	Sterile / Non-sterile	Reusable? Yes or No	Classification	Classification Rule Number per Annex IX	GMDN Code
185467	Vanguard™ 360 Distal Femoral Augment Block 72.5x15 RL/LM	Sterile	No	Iib	8	48067
185468	Vanguard™ 360 Distal Femoral Augment Block 75x15 RL/LM	Sterile	No	Iib	8	48067
185470	Vanguard™ 360 Distal Femoral Augment Block 80x15 RL/LM	Sterile	No	Iib	8	48067
185480	Vanguard™ 360 Distal Femoral Augment Block 55x15 LL/RM	Sterile	No	Iib	8	48067
185481	Vanguard™ 360 Distal Femoral Augment Block 57.5x15 LL/RM	Sterile	No	Iib	8	48067
185482	Vanguard™ 360 Distal Femoral Augment Block 60x15 LL/RM	Sterile	No	Iib	8	48067
185483	Vanguard™ 360 Distal Femoral Augment Block 62.5x15 LL/RM	Sterile	No	Iib	8	48067
185484	Vanguard™ 360 Distal Femoral Augment Block 65x15 LL/RM	Sterile	No	Iib	8	48067
185485	Vanguard™ 360 Distal Femoral Augment Block 67.5x15 LL/RM	Sterile	No	Iib	8	48067
185486	Vanguard™ 360 Distal Femoral Augment Block 70x15 LL/RM	Sterile	No	Iib	8	48067
185487	Vanguard™ 360 Distal Femoral Augment Block 72.5 x 15 LL/RM	Sterile	No	Iib	8	48067
185488	Vanguard™ 360 Distal Femoral Augment Block 75x15 LL/RM	Sterile	No	Iib	8	48067
185490	Vanguard™ 360 Distal Femoral Augment Block 80x15 LL/RM	Sterile	No	Iib	8	48067
185530	Vanguard 360 OsseoTi Tibial Sleeve Augment Type A, Extra Small	Sterile	No	Iib	8	48067
185531	Vanguard 360 OsseoTi Tibial Sleeve Augment Type A, Small	Sterile	No	Iib	8	48067
185532	Vanguard 360 OsseoTi Tibial Sleeve Augment Type A, Medium	Sterile	No	Iib	8	48067
185533	Vanguard 360 OsseoTi Tibial Sleeve Augment Type A, Large	Sterile	No	Iib	8	48067
185535	Vanguard 360 OsseoTi Tibial Sleeve Augment Type B, Extra Small	Sterile	No	Iib	8	48067
185536	Vanguard 360 OsseoTi Tibial Sleeve Augment Type B, Small	Sterile	No	Iib	8	48067
185537	Vanguard 360 OsseoTi Tibial Sleeve Augment Type B, Medium	Sterile	No	Iib	8	48067
185538	Vanguard 360 OsseoTi Tibial Sleeve Augment Type B, Large	Sterile	No	Iib	8	48067
185550	Vanguard 360 OsseoTi Tibial Sleeve Augment Type Full, Extra Small	Sterile	No	Iib	8	48067
185551	Vanguard 360 OsseoTi Tibial Sleeve Augment Type Full, Small	Sterile	No	Iib	8	48067
185552	Vanguard 360 OsseoTi Tibial Sleeve Augment Type Full, Medium	Sterile	No	Iib	8	48067
185553	Vanguard 360 OsseoTi Tibial Sleeve Augment Type Full, Large	Sterile	No	Iib	8	48067
185650	Vanguard 360 Tibial Small Cruciate Wing	Sterile	No	Iib	8	48067
185651	Vanguard 360 Tibial Large Cruciate Wing	Sterile	No	Iib	8	48067

Technical File – Declaration of Conformity

Table 1: GMDN Legend

GMDN	Description
32854	Orthopaedic bone pin, non-bioabsorbable
32832	Uncoated knee tibia prosthesis, metallic
48067	Knee arthroplasty wedge

Technical File – Declaration of Conformity

Table 2: DoC Revision History

Rev.	Date	Description
A	<i>3 December 2014</i>	Initial Release of KN-360-004. Existing Vanguard 360 class IIb components transferred from Technical File KN-003. The Vanguard 360 OsseoTi Tibial Sleeve Augments are new items being CE Marked, 185530-33; 185535-38; and 183550-53.
B	<i>17 September 2015</i>	GMDN code update, changing from 35074 to 32832 for part numbers 185210 – 185212.