aap Biomaterials GmbH
Lagerstraße 11-15 · D-64807 Dieburg · Germany

DECLARATION OF CONFORMITY

We
aap Biomaterials GmbH
Lagerstrasse 11-15
64807 Dieburg
Germany

herewith declare that the below mentioned products (sterile, class III, rule 17; GMDN code: 16966 Synthetic bone graft) meet the provisions of the Council Directive 93/42/EEC for medical devices and the Commission Directive 2003/32/EC. All supporting documentation is retained under the premises of the manufacturer. The conformity assessment route follows Annex II.3 and II.4.
A list of (harmonized) standards with documented evidence of compliance can be provided.

Objects of Declaration:

		Grain Size	Content	REF
Bone Substitute	BEGO OSS	0,5 – 1,0 mm	0,5 ml	57212
			1,0 ml	57213
			2,0 ml	57225
			3,0 ml	57214
			5,0 ml	57226
Bone Substitute	BEGO OSS	1,0 – 2,0 mm	0,5 ml	57227
			1,0 ml	57228
			2,0 ml	57215
			3,0 ml	57229
			5,0 ml	57216

Notified Body:
TÜV Süd Product Service GmbH, Ridlerstrasse 65, 80339 München, Germany, CE 0123

EC Certificate Full Quality Assurance System No. G1 11 06 58603 039, valid until 23 October 2015. EC Design Examination Certificate No. G7A 09 12 58603 032, valid until 20 January 2015.

The manufacturer, aap Biomaterials GmbH, is exclusively responsible for this Declaration of Conformity valid until 31 December 2013.

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Place, Date: Dieburg, 26 October 2012

Volker Stirnal
Director Quality Assurance and Regulatory Affairs

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