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 8; GMDN code 47201 Collagen haemostatic agent) meet the provisions of the Council Directive 93/42/EEC for medical devices. 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:

		Size	Content	REF
Type of product	BEGO Collagen Membrane	15 x 20 mm	1 piece	57221
	BEGO Collagen Membrane	20 x 30 mm	1 piece	57222
	BEGO Collagen Membrane	30 x 40 mm	1 piece	57223

Notified Body:
LGA InterCert GmbH, Zertifizierungsstelle Medizinprodukte, Tillystraße 2, 90431 Nürnberg, Germany, CE 1275

EC Certificate Full Quality Assurance System No. 1901866-006-000, valid until 11 December 2015.
EC Design Examination Certificate No. 1891715-007-000-001, valid until 18 June 2014.

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, 08 October 2012

Volker Stirnal
Director Quality Assurance and Regulatory Affairs

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