EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith grants

botiss biomaterials GmbH
Hauptstraße 28
15806 Zossen
Germany

for the scope

cerabone® and cerabone® plus (with sodium hyaluronate added) – bone substitute material originating from the raw material bovine bone for application in dental, oral and maxillofacial surgery (see attachment)

the

EC Design Examination Certificate

The examination of the design of the product by mdc has proven that the design meets the requirements according to

Annex II – Section 4 of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices as well as

Regulation (EU) 722/2012

concerning particular requirements with respect to medical devices manufactured utilizing tissues of animal origin.

This certificate is only valid in connection with a valid mdc certificate according to Annex II – excluding section 4 for the above mentioned products.

Valid from	2020-08-19
Valid until	2024-05-26
Registration no.	D1323300040
Report no.	P19-01431-158103
Stuttgart	2020-08-19

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten www.zlg.de
ZLG-BS-246.10.06

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Attachment of the certificate

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Product category	Product	Class
cerabone®	Content: 0.5 ml, Size: 0.5 - 1.0 mm Content: 1.0 ml, Size: 0.5 - 1.0 mm Content: 2.0 ml, Size: 0.5 - 1.0 mm Content: 5.0 ml, Size: 0.5 - 1.0 mm Content: 0.5 ml, Size: 1.0 - 2.0 mm Content: 1.0 ml, Size: 1.0 - 2.0 mm Content: 2.0 ml, Size: 1.0 - 2.0 mm Content: 5.0 ml, Size: 1.0 - 2.0 mm Block 20 x 20 x 10 mm	III
cerabone® plus (with sodium hyaluronate added)	Content: 0.5 ml, Size: 0.5 - 1.0 mm Content: 1.0 ml, Size: 0.5 - 1.0 mm Content: 0.5 ml, Size: 1.0 - 2.0 mm Content: 1.0 ml, Size: 1.0 - 2.0 mm	III

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