

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

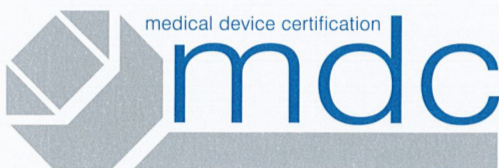
Regulation (EU) 722/2012

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



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Attachment of the certificate

No. D1323300040

Date 2020-08-19

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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




Head of Certification Body