



EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. CE 642222
Issued To: **BioScience GmbH**
Walsmühler Str. 18
Dümmer
19073
Germany

In respect of:
hyaDENT BG

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2016-04-22**

Date: **2021-04-22**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 642222

Issued To:

BioScience GmbH
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Product number	Description
BS091	hyaDENT BG

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Certificate History

Date	Reference Number	Action
22 April 2016	10158425	First issue.
06 February 2019	8576951	Traceable to NB 0086.
Current	3125646	Certificate Renewal Change to IFU with reduced indications

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