By Royal Charter

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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Supplementary Information to CE 642222

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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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