

EC Certificate - Full Quality Assurance System

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

No. **CE 641036**
Issued To: **BioScience GmbH**
Walsmühler Str. 18
Dümmer
19073
Germany

In respect of:

Design, development and manufacture of Hyaluronic Acid based medical devices

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II 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: **2021-04-20**

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 approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

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

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Supplementary Information to CE 641036

Issued To:

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Number	Device Name	Intended Purpose per IFU
Class III		
MD 0204 MDS 7006 MDS 7009	Hyacorp Endogel	See CE 641232
MD 0402 MDS 7006 MDS 7009	Hyadent BG	See CE 642222
MD 0402 MDS 7006 MDS 7009	Hyadent	See CE 642487

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 641036**
 Date: **2021-04-20**
 Issued To: **BioScience GmbH
 Walsmühler Str. 18
 Dümmer
 19073
 Germany**

Certificate History

Date	Reference Number	Action
22 April 2016	8412240	First Issue.
30 June 2016	8413647	Addition of Significant Subcontractor 'BioPolymer GmbH & Co KG, Walsmühler Str. 18, Dümmer, 19073, Germany' for the activities of Inspection and Testing. Modification of Scope to remove 'for dental applications'.
06 February 2019	8576951	Traceable to NB 0086. Administrative change to subcontractor activity type, 'Inspection Testing' to 'Final Inspection Testing' for BioPolymer GmbH & Co KG.
Current	3174927	Certificate renewal. Crucial supplier address change from "Shiseido Co LTD, 1-1-16, Higashi Shimbashi, Minatoku, Tokyo 105-0021 Japan" to "Shiseido Co LTD, 7-5-5, Ginza, Chuo-ku, Tokyo 104-0061, Japan". Clarification of scope to confirm in a table the specific devices under certification.

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Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

23 March 2022	3622280	A CE certificate (CE 642487) is expired, therefore HyaDent device is removed from the certificate scope.
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23 March 2022

BioScience GmbH
Walsmühler Str. 18
Dümmer
19073
Germany

To whom it may concern,

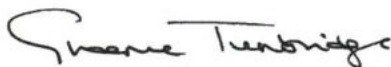
The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 641036	93/42/EEC Annex II excluding Section 4	3622280	Scope reduced. The HyaDent device is removed from the device table and scope.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,



Graeme Tunbridge
Senior Vice President, Medical Devices