By Royal Charter

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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Supplementary Information to CE 641036

Issued To:

BioScience GmbH
Walsmühler Str. 18
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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

First Issued: **2016-04-22** Date: **2021-04-20** Expiry Date: **2024-05-26**

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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

Subcontractor:	**Service(s) supplied**
BioPolymer GmbH & Co KG Walsmühler Str. 18 Dümmer 19073 Germany	**Final Inspection** **Testing**
Shiseido Co LTD 7-5-5, Ginza Chuo-ku Tokyo 104-0061 Japan	**Crucial Supplier**
team-pharma Volkmar Lippold GmbH Hauptstr. 3a Dümmer 19073 Germany	**Manufacture** **Moist Heat Sterilization**

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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.