



EC Design-Examination Certificate

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

No. CE 641232
Issued To: **BioScience GmbH**
Walsmühler Str. 18
Dümmer
19073
Germany

In respect of:
HYAcrop endo gel

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: **2016-06-30**

Date: **2021-05-11**

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

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Supplementary Information to CE 641232

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Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
BS080	HYAcorp endo gel	Syringe 10ml Without needle	HYAcorp endo gel is intended to be used for laparotomic or laparoscopic abdominal interventions, and for hysteroscopic interventions for reduction of post-surgical adhesion formation.	Class III Implantable
BS081		Syringe 10ml Short needle		
BS082		Syringe 10ml Long needle		
BS084		Syringe 2ml Without needle		

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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.

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Certificate History

Date	Reference Number	Action
30 June 2016	10158195	First Issue.
06 February 2019	8576951	Traceable to NB 0086.
Current	3141663	Certificate Renewal. Main scope and device table updated to confirm the intended purpose per IFU in the device table. Following contraindications added in the IFU: bowel resection and anastomose.

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