

EC Design-Examination Certificate

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

No.**CE 674830****Issued To:**

Integra LifeSciences Corporation
1100 Campus Road
Princeton
New Jersey
08540
USA

In respect of:

DuraSeal® Dural Sealant System

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: 2017-09-05**Date: 2020-12-17****Expiry Date: 2023-06-12**

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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.

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Supplementary Information to CE 674830

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Product Code	Description	Intended Use	Classification
DSD5001	DuraSeal Dural Sealant System 5ml (single kit)	The DuraSeal Dural Sealant System is intended for use as an adjunct to standard methods of dural repair, such as sutures, to provide watertight closure.	Class III
DSD5005	DuraSeal Dural Sealant System 5ml (box with 5 kits)		

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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
05 September 2017	10169784	First issue; Transfer from another notified body.
26 March 2018	8858199	Change to product name in scope from DuraSeal® Cranial Sealant System to DuraSeal® Dural Sealant System.
12 June 2018	8867596	Certificate Renewal.
05 September 2018	8939836	Addition of manufacturing and packaging subcontractor of Availmed S.A. de C.V.C. Industrial Lt. 001 Mz.105 No. 20905 Int. A col. Cd. Industrial, Tijuana Baja, California, 22444, Mexico and Sterilization subcontractor of Synergy Health AST, LLC 9020 Activity Road, Suite D, San Diego, California, 92126, USA.
12 March 2019	8680134	Traceable to NB 0086.
Current	3218825	Address change from: 311 Enterprise Drive, Plainsboro, New Jersey 08536 USA To: 1100 Campus Road, Princeton, New Jersey 08540 USA Update in supplementary table format to include intended purpose and device classification

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