By Royal Charter

EC Design-Examination Certificate

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

No. **CE 669964**

Issued To: **Integra LifeSciences Corporation**
1100 Campus Road
Princeton
New Jersey
08540
USA

In respect of:

DuraSeal® Xact 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):

Digitally signed by Gherman Irina
Date: 2022.10.19 13:26:57 EEST
Reason: MoldSign Signature
Location: Moldova

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2017-09-05** Date: **2020-12-17** Expiry Date: **2024-05-26**

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Supplementary Information to CE 669964

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Product Code	Description	Intended Use	Classification
203001	DuraSeal Xact Sealant System 3ml (single kit)	The DuraSeal Xact System is indicated for use during spine procedures as an adjunct to standard methods of dural repair, such as sutures, to provide watertight closure.	Class III
204003	DuraSeal Xact Sealant System 3ml (box with 5 kits)		

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Certificate History

Date	Reference Number	Action
05 September 2017	10169784	First issue; Transfer from another notified body.
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.
25 May 2020	9771333	Certificate Renewal.
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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