**EC DECLARATION OF CONFIRMITY**

Annex II, Clause 3 of Council Directive 93/42/EEC concerning Medical Devices

**Manufacturer:**

Australia by SDI Limited
Bayswater
Victoria 3153
Australia

EC Certificate No: 1 32 25 45735 817
Valid until: 2023-12-03

GMDN CODE: 35875

UMDNS CODE: 17-619

**Manufacturing Facility:**

SDI Germany GmbH
Hansestrasse 85
51149 Cologne
Germany

| | | | |
|---|---|---|---|
| Product Family: | Glsass ionomer restorative material | Product: | Glass ionomer material |
| | | CE Mark Date: | Sept. 23, 2016 |
| EC Product Class: | II | | |
| Rule: | 8 | | |

Per Annex IX of the Medical Device Directive

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Declaration of conformity

SDI Germany GmbH declares that devices listed on the attached Device Schedule conform to the relevant provision of the EC Council Directive 93/42/EEC dated 14 June 1993 and are in accordance with ISO 13485:2003, Medical devices – Quality management systems – Requirements for regulatory purposes, as implemented by the European Union`s Medical Devices Regulations and verified by TuV SuD Product Service GMBH, CE 0123.

Signature | Director Regulatory Affairs (Title) | St.Paul, Minnesota USA (Location) | 2 April 2019 (Date)

EC DECLARATION OF CONFORMITY

**Product Family:** Glass ionomer material
**EC Product Class (Per Annex IX Rules):** Class: II Rule: 8
**Product:**

| Item | Catalogue/Order Number |
|---|---|
| "riva self cure" - glass ionomer restorative material | 10282490015 |
| "riva light cure" – light cured glass ionomer restorative material | 10282490025 |
| "riva luting" – glass ionomer luting cement | 10282490019 |