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# MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES)
REGULATIONS 2002

This is a declaration made in accordance with:

(i) The requirements of Clause 6.6 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 relating to the stated device.

(ii) The provision of Council Directive 93/42/EEC Annex II Notified Body ID Number of DQS 0297

**Manufacturer's Name:** SDI LIMITED

**Manufacturer's Address:** 3-15 BRUNSDON STREET
BAYSWATER, VICTORIA 3153, AUSTRALIA

**Representative Address in Europe:** Southern Dental Industries Ltd
Block 8, St. Johns Court
Swords Road
Santry, Dublin
IRELAND

**Declare under our sale responsibility that the products:**

Riva Coat

**Device risk class and rule:** Class I, Rule No. 5 (European Classification)
Class I, Rule No 3.1 (TGA Classification)

**GMDN Code and Term:** 31780
Dental Material, pit/fissure sealing, polymer based.

*For each kind of medical device to which the Declaration of Conformity (not requiring assessment from the Secretary) procedures have been applied the product quality assurance procedures have also been applied. Each medical device complies with the applicable provisions of the essentials principles, the classification rules before being supplied.*



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**To which this declaration relates is in conformity with following standard/s/ or other normative document/s/:**

| | |
|---|---|
| AU Q00053 | TGA issued: Conformity Assessment Certificate – Full Quality Assurance Procedures |
| ISO 9001 | Quality systems Model for quality assurance in design, development, production, installation and servicing |
| ISO 13485 | Medical devices - Quality management systems - Requirements for regulatory purposes |

Melbourne, 29 June 2015

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**RAY CAHILL**
Technical Director
SDI Limited

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