Your Smile. Our Vision.

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.

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 Conditioner

Device risk class and rule: Class IIa, Rule No 3.2 (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.

SDI Your Smile. Our Vision.

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

.....

RAY CAHILL
Technical Director
SDI Limited

REGISTRATION NO 6672 AU
SDI Limited
3-13 Brunsdon St.
Bayswater 3153
Victoria
Australia
ACN: 008 075 581