SDI 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.

(ii) The provision of Council Directive 93/42/EEC Annex II

Notified Body Name: DQS Medizinprodukte GmbH

Notified Body Identification Number: 0297

Notified Body Address: August-Schanz-Straβe 21, 60433 Frankfurt am Main Germany.

Manufacturer's Name: SDI LIMITED

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

Representative Address in Europe: SDI Germany GmbH
Hansestrasse 85
D-51149, Cologne
Germany

Declare under our sale responsibility that the products:

Riva Bond LC

Riva Light Cure

Riva Light Cure HV

Riva Luting

Riva Luting Plus

Riva Protect

Riva Silver

Riva Self Cure

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Riva Self Cure HV

Riva CEM

Everfix

Device risk class and rule: Class IIa, Rule No. 8
Class IIa, Rule No 3.4

GMDN Code and Term: 16704 Dental Glass Ionomer Cement.

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.

Validity Period: This declaration of conformity is valid for the period as per the expiration date of the EC Certificate issued by DQS Medizinprodukte GmbH

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

ISO 4049:2009	Dentistry - Polymer-based Filling, Restorative and Luting Materials
ISO 6874:2015	Dental Resin-based Pit and Fissure Sealants
ISO 9917-1:2007	Dentistry Water-Based Cements - Part 1: Powder/Liquid Acid-base Cements
ISO 9917-2:2010	Dental Water-based Cements - Part 2 - Light-activated cements
ISO 9001:2008	Quality systems Model for quality assurance in design, development, production, installation and servicing
ISO 13485:2003	Medical devices - Quality management systems – Requirements for regulatory purposes
EN ISO 13485:2012+AC:2012	Medical devices - Quality management systems - Requirements for regulatory purposes

SDI Limited A.C.N. 008 075 581, A.B.N. 27 008 075 581

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SDI

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Melbourne, 6 July 2017

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RAY CAHILL
Technical Director
SDI Limited

SDI Limited A.C.N. 008 075 581, A.B.N. 27 008 075 581

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