



Your Smile. Our Vision.

MANUFACTURER'S DECLARATION OF CONFORMITY

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-Straße 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 Star
Riva Star Aqua

Scope of application: All batches

Device risk class and rule: Class IIa, Rule No 3.1, 2(c) (Australia-TGA classification)
Class IIa, Rule no. 5 (European Classification)

GMDN Code and Term: 45232 Dental material, desensitising resin.

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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Quality Management System Certificates:

Assessment Body and Certificate Number:

DQS Medizinprodukte GmbH
August-Schanz-Straße 21, 60433
Frankfurt am Main, Germany.

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 13485:2016 (MDSAP Audit Model Edition 2)	Medical devices - Quality management systems – Requirements for regulatory purposes
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices -- Application of risk management to medical devices
ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
ISO 7405:2018	Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
ISO 10993-1:2018	Biological evaluation of medical devices – Part1: Evaluation and testing within a risk management process

Melbourne, 17 November 2020



RAY CAHILL

Chief Quality and Compliance Officer
SDI Limited