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-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:

Alloybond

Bonding Resin

Go!

Stae

Etch and Bond kit

Zipbond Universal

Device risk class and rule:	Class IIa, Rule No. 8, Subclause 1 (European Classification, Dir. 93/42/EEC) Class IIa, Rule No 3.4 (TGA Classification)
GMDN Code and Term:	34782 Dental bonding agent, polymer based.

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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 13485:2016	Medical devices - Quality management systems – Requirementsfor 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
ISO / TS 11405:2015	Dental materials - Testing of adhesion to tooth structure
ISO/FDIS 29022:2012	Dentistry –Adhesion—Notched - Edge Shear Bond Strength Test

Melbourne, 24 April 2019



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RAY CAHILL
Chief Quality and Compliance Officer
SDI Limited