SDI

YOUR SMILE. OUR VISION.

SDI LIMITED ACN 008 075 581 | ABN 27 008 075 581
HEAD OFFICE 3-15 BRUNSDON STREET, BAYSWATER. PO BOX 314, VICTORIA, 3153 AUSTRALIA.
TOLL FREE 1800 337 003 | TELEPHONE +61 3 8727 7111
FAX +61 3 8727 7222 | info@sdi.com.au | www.sdi.com.au

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 Regulation (EU) 2017/745 on medical devices (MDR)

Notified Body Name: **Notified Body**	DQS Medizinprodukte GmbH
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
SRN Code	AU-MF-000024633
Representative Address in Europe:	SDI Germany GmbH Hansestrasse 85 D-51149, Cologne Germany
SRN Code	DE-AR-000023386
Swiss Authorized Representative **CH-REP** **SRN Code** **Address**	SMQS SMQS by Arnold Bott AG CHRN-AR-20001948 Industriestrasse 59, 8152 Glattbrugg Switzerland

Declare under our sale responsibility that the products:

Super Etch

Super Etch LV

Etch & Bond

Acid Etch Gel

Acid Etch Liquid

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Etchant Gel

Etchant Liquid

Etching Gel

Etching Gel 37% Phosphoric Acid

Device risk class and rule: Class II a, Rule No. 8 (European Classification)
Class IIa, Rule 3.4 (TGA Classification)

GMDN Code and Term: 36153 Dental etching composite.

MDN Code 1103

CND Code Q010101

Basic UDI-DI TBC (to be confirmed)

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 (MDSAP Audit Model Edition 2)	Medical devices - Quality management systems - Requirements for regulatory purposes
DIN EN ISO 13485:2016+AC2017-07 EN13485:2016+AC:2016 ISO13485:2016	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 10993-1:2018	Biological evaluation of medical devices – Part 1: evaluation and testing within a risk management process

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ISO 7405:2018	Dentistry – Evaluation of biocompatibility of medical devices used in dentistry



Melbourne, 28 September 2022

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RAY CAHILL
Chief Quality and Compliance Officer
SDI Limited