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:	DQS Medizinprodukte GmbH
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
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	SMQS
CH-REP	SMQS by Arnold Bott AG
SRN Code	CHRN-AR-20001948
Address	Industriestrasse 59, 8152 Glattbrugg Switzerland

Declare under our sale responsibility that the products:

Aura / Aura Bulk Fill / Aura Easy / Aura eASYflow
Glacier
Ice
Luna / Luna 2 / Luna Flow / Luna Flow LV
Wave / Wave HV / Wave MV
LC Opaquer
Rok
Shade Modification Kit

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Device risk class and rule:

Class II a, Rule No. 8, Subclause 1 (EU MD 2017/745)
Class IIa, Rule 3.4 (TGA Classification)

GMDN Code and Term: 38649
Dental material, filling/restorative, polymer based

MDR Code MDN 1103

CND Code Q010101

Basic UDI-DI 9336472COMPOSITEW3

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.

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 14971:2019	Medical devices – Application of risk management to medical devices
ISO 15223-1:2021	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
ISO 7405:2018	Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
ISO 4049:2019	Dentistry- Polymer-based filling, restorative and luting materials.

Melbourne, 28 September 2022

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RAY CAHILL
Chief Quality and Compliance Officer
SDI Limited

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