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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 of conformity is 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) (EU) MDR 2017/745 Annex IV

Manufacturer's Name:	SDI LIMITED
Manufacturer's Address:	3-15 Brunsdon Street Bayswater, Victoria 3153, Australia
SRN	AU-MF-000024633
SRN	AU-PR-000037885
Representative Address in Europe:	SDI Germany GmbH Hansestrasse 85 D-51149, Cologne Germany
SRN	DE-AR-000023386
Notified Body Name:	DQS Medizinprodukte GmbH
Notified Body Identification Number:	0297
Notified Body Address:	August-Schanz-Straβe 21, 60433 Frankfurt am Main Germany.
Swiss Authorized Representative	SMQS
CH-REP	SMQS by Arnold Bott AG
CHRN	CHRN-AR-20001948
Address	Industriestrasse 59, 8152 Glattbrugg Switzerland

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Name of Device	Basic UDI-DI
Stela Automix System Intro Kit	**9336472101135870C2FF**
Stela Capsule System Intro Kit	**9336472101135870C2FF**
Stela Primer	**9336472101135870C2FF**
Stela Automix	**9336472101135870C2FF**
Stela Capsule	**9336472101135870C2FF**

Device UDI-DI & Accessories

Catalogue number	Description	UDI-DI (GS1 code)
8640001	Stela Automix 1 Syr Refill	9336472002367
8640002	Stela Automix Intro Kit	9336472002374
8640003	Stela Capsules Refill 50 Cap	9336472002381
8640004	Stela Capsules Intro Kit	9336472002398
8640006	Stela Primer Refill 5ml Bt	9336472002411
9900195	Stela Capsules Sample	9336472002428

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Device Figure

Stela Automix System	
Stela Capsule System	

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Stela Automix	
Stela Primer	
Stela Capsule	

Device risk class and rule:

(1) TGA: Class IIa, Rule 3.4 surgically invasive medical device that is intended for long-term use; and intended by the manufacturer to be placed in the teeth of a patient

(2) EU (MDR 2017/745), Annex VIII): Class IIa, Rule No.8, "Long term surgically invasive intended to be placed in the teeth"

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GMDN Code and Term ***Stela Automix, Stela Capsule, Stela Automix System, Stela Capsule System, Stela Primer***
35870 Dental material, filling/restorative, polymer based

EMDN Code Q01010103

MDN Code MDN 1103

MDS Code **MDS 1011**

We hereby declare the medical device and its variants specified above meet the provision of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 and the Regulation (EU) MDR 2017/745. This declaration is supported by the Quality Management System approvals to EN ISO 13485:2016+A11:2021 and MDSAP ISO13485:2016 issued by DQS Medizinprodukte GmbH. All supporting documentation is retained at SDI Limited, Victoria, Australia

Place and Date of Issue	Victoria, Australia. January 2024
Name	Lyn Chau
Position	Regulatory Systems Manager
Signature	DocuSigned by: Lyn Chau 183C749BDB70450... 

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