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 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 SRN AU-MF-000024633
Representative Address in Europe:	SDI Germany GmbH Hansestrasse 85 D-51149, Cologne Germany SRN 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:

Radii Cal

Radii Cal Control Section

Radii Cal Charger

Radii Cal Barrier sleeves

Radii Cal replacement battery

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Radii Cal light shield

Radii Cal CX

Radii Cal CX Control Section

Radii Cal CX Charger

Radii Cal CX Barrier sleeves

Radii Cal CX replacement battery

Radii Cal CX light shield

Radii Plus

Radii Plus diagnostic LED attachment

Radii Plus Standard LED attachment

Radii Plus Orthodontic LED attachment

Radii Plus Contra angle standard LED attachment

Radii Plus Single tooth bleaching LED attachment

Radii Plus Control section

Radii Plus light shield

Radii Plus Bleach Arch Stand

Radii Plus Bleach Arch Kit

Radii Plus Bleach Arch Barrier Sleeve

Radii Plus Bleach Arch Light Shield

Radii Plus Replacement battery

Radii Plus Diagnostic Adapter Tip

Radii Plus charger

Radii Plus Barrier sleeves

Radii Xpert

Radii Xpert Bleach Arch attachment

Radii Xpert Control section

Radii Xpert Diagnostic LED attachment

Radii Xpert LED attachment

Radii Xpert Orthodontic LED attachment

Radii Xpert Multiwave attachment

Radii Xpert Barrier sleeves

Radii Xpert light shield

Radii Xpert replacement battery

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Radii Xpert charger

LED Radiometer

Radiometer X

Device risk class dental **and rule:** Class I , Rule No.13 (European Classification)
Class I, Rule No 4.1 (TGA Classification)

GMDN Code and Term: 35775
Light, polymerisation activator

MDR Code 1214-1

CND Code Q010104

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.

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
ISO 7405:2018	Dentistry – Evaluation of biocompatibility of medical devices used in dentistry
IEC 60601-1	Medical Electrical Equipment: Part 1- General requirements for safety.
IEC 60601-1:2010 + Emenda 1:2016	Medical Electromedical Equipment Part 1: General Requirements for Basic Safety and Essential Performance
IEC 60601-1-2:2010	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

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IEC 60601-1-6:2011	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 60601-1-9:2010 + Emenda 1:2014	Medical electrical equipment Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design
IEC 60601-2-57:2015	Medical Electrical Equipment - Part 2-57: Particular Requirements for The Basic Safety And Essential Performance Of Non-Laser Light Source Equipment Intended For Therapeutic, Diagnostic, Monitoring And Cosmetic/Aesthetic Use

Melbourne, 27 September 2022

RAY CAHILL
Chief Quality and Compliance Officer
SDI Limited