



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

SDI Limited

3-15 Brunsdon Street
Bayswater, Victoria 3153
Australia

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Dental restorative materials and dental etching agent products according to annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	350555 MR2
Certificate unique ID	170776114
Effective date	2021-05-18
Expiry date	2024-05-26
Frankfurt am Main	2021-05-18

DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



Annex to certificate

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Device family	GMDN Code	Class
<i>Dental amalgam alloys according to ISO 24234:2004, comprising of the following products:</i>		
Permite: capsules, powder & tablets Lojic Plus: capsules, powder & tablets GS 80: capsules, powder & tablets New Ultrafine: powder F400: capsules, powder & tablets GS 80 Spherical: capsules Ultracaps +: capsules SDI Admix alloy capsules SDI Spherical alloy capsules SDI Alloy powder	34836	Ila
<i>Dental resin-based filling material according to ISO 4049:2000, comprising of the following products:</i>		
Wave: syringes, complets Wave MV: syringes, complets Composite Restorative Material – Nano Flow Wave HV: syringes, complets Glacier: syringes, complets LC-Opaquer: syringes Rok: syringes, complets Ice: syringes, complets Composite Restorative Material – Nano Hybrid Shade modification kit ; syringes Aura: syringes, complets Composite Restorative Material – Bulk Fill Luna: syringes, complets Aura Easyflow Luna Flow Luna Flow LV LUNA 2	38649	Ila
<i>Dental resin-based pit and fissure sealant according to ISO 6874:2005, comprising of the following products.</i>		
Conseal Series: bottles, syringes, complets	37247	Ila
<i>Dental compomer, comprising of the following products:</i>		
Freedom: syringes, bottles, complets	38649	Ila



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Device family	GMDN Code	Class
<i>Dentin/Enamel adhesive, comprising of the following products:</i>		
STAE: bottles, unidose Dental Adhesive – Total Etch Alloybond: bottles Bonding Resin: bottles Etch and Bond Kit: bottles GO: bottles, unidose Nano Dental Adhesive – Self etch Zipbond Universal / Universal Adhesive	34782	Ila
<i>Dental gel etchant based on phosphoric acid, comprising of the following products:</i>		
Super-Etch LV Super-Etch: syringes, bottles Etching Gel 37% Phosphoric Acid Etchant (liquid): bottles	36153	Ila
<i>Dental etching agent of following products:</i>		
Pola Office: powder & liquid Pola Professional 35% Pola Office +: syringe Pola Professional 37.5% Pola Day CP: syringe Norblanc Office: powder & liquid Norblanc Office Automix: syringe	17737	Ila



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Device family	GMDN Code	Class
<i>Dental glass ionomer cements according to ISO 9917-1:2003, comprising of the following products:</i>		
Riva Self cure: capsules, powder & liquid Riva Self Cure HV: capsules, powder & liquid Riva Protect: capsules, powder & liquid Riva Light Cure: capsules, powder & liquid Riva Light Cure HV: capsules, powder & liquid Riva Silver: capsules, powder & liquid Riva Luting: capsules, powder & liquid Riva Luting Plus: capsules, powder & liquid Riva Bond LC: capsules, powder & liquid Riva CEM Riva CEM AUTOMIX EVERFIX Resin Reinforced Glass Ionomer Cement	16704	Ila
<i>Self-etching, self-adhesive resin cement, comprising of the following products</i>		
SeT: capsules SetPP: syringes	35870	Ila
<i>Dental material, desensitising resin:</i>		
Riva Star: capsule, bottle Riva Star Aqua: capsule, bottle	45232	Ila