



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EG Bescheinigung

Vollständiges Qualitätssicherungssystem
Richtlinie 93/42/EWG über Medizinprodukte (MDD), Anhang II ohne (4)
(Produkte in Klasse IIa, IIb oder III)

Nr. G1 055249 0010 Rev. 01

Hersteller:

SAREMCO DENTAL AG

Gewerbestrasse 4
9445 Rebstein
SCHWEIZ

Betriebsstätte(n):

SAREMCO DENTAL AG
Gewerbestrasse 4, 9445 Rebstein, SCHWEIZ

Produktkategorie(n):

**Zahnfüllungs- und
Zahnversiegelungskunststoffe,
Haftvermittler für Zahnfüllungsmaterialien,
Zemente für die Zahnrestauration, Ätzgele,
Dentale Kunststoffe für den 3D-Druck,
Befestigungskunststoffe für
kieferorthopädische
Regulierungssysteme**

Die Zertifizierstelle der TÜV SÜD Product Service GmbH bescheinigt hiermit, dass der genannte Hersteller ein Qualitätssicherungssystem für die Auslegung, die Fertigung und die Endkontrolle der betreffenden Produkte / Produktkategorien entsprechend MDD Anhang II anwendet. Dieses Qualitätssicherungssystem erfüllt die Anforderungen dieser Richtlinie und unterliegt der regelmäßigen Überwachung. Zum Inverkehrbringen von Klasse III Produkten ist zusätzlich eine Bescheinigung nach Anhang II (4) erforderlich. Umseitige Hinweise sind zu beachten.

Bericht Nr.:

713165928

Gültig ab:

2019-11-26

Gültig bis:

2024-05-26

Datum,

2019-11-26

Christoph Dicks

Head of Certification/Notified Body



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ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 055249 0010 Rev. 01

Manufacturer:

SAREMCO DENTAL AG

Gewerbestrasse 4
9445 Rebstein
SWITZERLAND

Facility(ies):

SAREMCO DENTAL AG
Gewerbestrasse 4, 9445 Rebstein, SWITZERLAND

**Product Category(ies): Dental Filling Materials and Fissure
Sealants, Adhesives for Dental Filling
Materials, Cements for Dental Restoration,
Etching Gels, Dental Resins for 3D-Printing,
Materials for Orthodontic Appliances**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

713165928

Valid from:

2019-11-26

Valid until:

2024-05-26

Date,

2019-11-26

Christoph Dicks
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



Product Service

TÜV SÜD Product Service GmbH • Ridlerstraße 65 • 80339 Munich • Germany

**Add value.
Inspire trust.**

Munich, 2024-10-17
Order no.: 713349453_2

Confirmation concerning certificate G1 055249 0010 Rev. 01, CL 055249 0015 Rev. 00 and related medical devices

We confirm that the following certificate:

G1 055249 0010 Rev. 01
covered by Confirmation Letter
CL 055249 0015 Rev. 00 (valid until 2028-12-31)

issued to the legal medical device manufacturer:

SAREMCO DENTAL AG
Gewerbestrasse 4
9445 Rebstein
SWITZERLAND

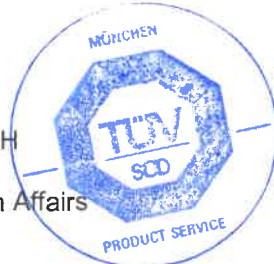
covers the Directive 93/42/EEC on Medical Devices Annex II excluding (4) with the scope:

Dental Filling Materials and Fissure Sealants, Adhesives for Dental Filling Materials, Cements for Dental Restoration, Etching Gels, Dental Resins for 3D-Printing, Materials for Orthodontic Appliances

and the following medical devices:

Refer to ANNEX MDD, pages 2 to 7 of this letter.

R. Köhler
Randolf Köhler
TÜV SÜD Product Service GmbH
PS-MHS-AU-9
Medical Health Services Foreign Affairs



Registered Office: Munich
Trade Register Munich HRB 85 742
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(Germany) at www.tuvsud.com/imprint
ID: 4527

Supervisory Board:
Holger Lindner (Chairman)

Board of Management:
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TUV®

Effective: 28 Nov 2018 Jul 2024

TÜV SÜD Product Service GmbH
Foreign Affairs
Ridlerstraße 65
80339 Munich
Germany

Page 1 of 7



ANNEX MDD

List of Products (MDR Transitional Provisions)

Basic-UDI-DI	Article Number	Name of Medical Device	Class	EMDN Code	GMDN Code	Legal Manufacturer	Unique identification number of the certificate issued by a forementioned office
++D9311000Y9	7011	els extra low shrinkage flow SW Tipdose	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7013	els extra low shrinkage flow A1 Tipdose	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7014	els extra low shrinkage flow A2 Tipdose	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7015	els extra low shrinkage flow A3op. Tipdose	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7016	els extra low shrinkage flow A3.5/B4 Tipdose	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7017	els extra low shrinkage flow A4 Tipdose	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7018	els extra low shrinkage flow B1 Tipdose	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7019	els extra low shrinkage flow C2 Tipdose	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7111	els extra low shrinkage flow SW syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7113	els extra low shrinkage flow A1 syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7114	els extra low shrinkage flow A2 syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7115	els extra low shrinkage flow A3op. syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7116	els extra low shrinkage flow A3.5 syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7117	els extra low shrinkage flow A4 syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7118	els extra low shrinkage flow B1 syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010



Basic-UDI-DI	Article Number	Name of Medical Device	Class	EMDN Code	GMDN Code	Legal Manufacturer	Unique identification number of the certificate issued by a forementioned office
++D9311000Y9	7119	els extra low shrinkage flow C2 syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7135	els extra low shrinkage flow economy kit syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7201	mhc IB syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7210	mhc A1 syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7220	mhc A2 syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7225	mhc A3 syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7227	mhc A3op. syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7230	mhc A3.5/B4 syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7235	mhc B1 syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7240	mhc B2 syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7250	mhc C2 syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7270	mhc D3 syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9312000YG	7310	microcid etchant gel syringe	IIa	Q01010104	36153	Saremco Dental AG	G1 055249 0010
++D9312000YG	7315	microcid etchant gel syringe refill-syringe	IIa	Q01010104	36153	Saremco Dental AG	G1 055249 0010
++D9312000YG	7413	James-2	IIa	Q01010104	34782	Saremco Dental AG	G1 055249 0010
++D9312000YG	7414	James-2 sample	IIa	Q01010104	34782	Saremco Dental AG	G1 055249 0010
++D9313000YP	7463	els extra low shrinkage cem	IIa	Q01010102	35870	Saremco Dental AG	G1 055249 0010



Basic-UDI-DI	Article Number	Name of Medical Device	Class	EMDN Code	GMDN Code	Legal Manufacturer	Unique identification number of the certificate issued by a forementioned office
++D9313000YP	7480	csp ceramic silane primer set	IIa	Q01010102	62474	Saremco Dental AG	G1 055249 0010
++D9313000YP	7481	csp ceramic silane base	IIa	Q01010102	62474	Saremco Dental AG	G1 055249 0010
++D9313000YP	7482	csp ceramic silane activator	IIa	Q01010102	62474	Saremco Dental AG	G1 055249 0010
++D9312000YG	7551	cmf etch syringe	IIa	Q01010104	36153	Saremco Dental AG	G1 055249 0010
++D9312000YG	7552	cmf prime	IIa	Q01010104	36153	Saremco Dental AG	G1 055249 0010
++D9312000YG	7553	cmf bond	IIa	Q01010104	36153	Saremco Dental AG	G1 055249 0010
++D9312000YG	7554	cmf prime stock package, 4x 2.5ml	IIa	Q01010104	36153	Saremco Dental AG	G1 055249 0010
++D9312000YG	7555	cmf bond stock package, 4x 2.5ml	IIa	Q01010104	36153	Saremco Dental AG	G1 055249 0010
++D9312000YG	7559	cmf etch refill-syringe	IIa	Q01010104	36153	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7750	els extra low shrinkage paintart economy kit	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7751	els extra low shrinkage paintart white syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7752	els extra low shrinkage paintart yellow syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7753	els extra low shrinkage paintart brown syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7754	els extra low shrinkage paintart grey syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7755	els extra low shrinkage paintart blue syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010



Basic-UDI-DI	Article Number	Name of Medical Device	Class	EMDN Code	GMDN Code	Legal Manufacturer	Unique identification number of the certificate issued by a forementioned office
++D9311000Y9	7756	els extra low shrinkage paintart red syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7757	els extra low shrinkage paintart incisal syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7864	els extra low shrinkage bulkfill syringe	IIa	Q01010103	34782	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7865	els extra low shrinkage bulkfill Tipdose	IIa	Q01010103	34782	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7935	els extra low shrinkage flow A2, A3op. tip samples, 2 x 0.3g	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	7937	els extra low shrinkage flow A3op. tip sample, 0.30g	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9312000YG	8012	els extra low shrinkage duo-bond 5ml	IIa	Q01010103	34782	Saremco Dental AG	G1 055249 0010
++D9312000YG	8013	els extra low shrinkage uni-bond 5ml	IIa	Q01010103	34782	Saremco Dental AG	G1 055249 0010
++D9312000YG	8014	els extra low shrinkage uni-bond 1ml sample	IIa	Q01010103	34782	Saremco Dental AG	G1 055249 0010
++D9313000YP	8016	Peek-Primer FP	IIa	Q01010102	62474	Saremco Dental AG	G1 055249 0010
++D9311000Y9	8024	apt advanced polymer technology A1 Tipdose	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	8025	apt advanced polymer technology A2 Tipdose	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	8026	apt advanced polymer technology A3 Tipdose	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	8027	apt advanced polymer technology A3.5/B4 Tipdose	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9311000Y9	8028	apt advanced polymer technology flow A2 syringe	IIa	Q01010103	35870	Saremco Dental AG	G1 055249 0010



Basic-UDI-DI	Article Number	Name of Medical Device	Class	EMDN Code	GMDN Code	Legal Manufacturer	Unique identification number of the certificate issued by a forementioned office
++D9311000Y9	8029	apt advanced polymer technology flow A3 syringe	Ila	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9312000YG	8030	apt advanced polymer technology unibond 5ml	Ila	Q01010104	34782	Saremco Dental AG	G1 055249 0010
++D9311000Y9	8031	apt advanced polymer technology A2,A3 tip samples, 2 x 0.37g	Ila	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9312000YG	8040	apt advanced polymer technology unibond 1ml sample	Ila	Q01010104	34782	Saremco Dental AG	G1 055249 0010
++D9311000Y9	8041	els extra low shrinkage flow Wop./SW++ syringe	Ila	Q01010103	35870	Saremco Dental AG	G1 055249 0010
++D9314000YW	8051	saremco print CROWNTEC A3	Ila	Q010205	16730	Saremco Dental AG	G1 055249 0010
++D9314000YW	8052	saremco print CROWNTEC A2	Ila	Q010205	16730	Saremco Dental AG	G1 055249 0010
++D9314000YW	8053	saremco print CROWNTEC B3	Ila	Q010205	16730	Saremco Dental AG	G1 055249 0010
++D9314000YW	8054	saremco print CROWNTEC D3	Ila	Q010205	16730	Saremco Dental AG	G1 055249 0010
++D9314000YW	8055	saremco print CROWNTEC A3.5	Ila	Q010205	16730	Saremco Dental AG	G1 055249 0010
++D9314000YW	8056	saremco print CROWNTEC B2	Ila	Q010205	16730	Saremco Dental AG	G1 055249 0010
++D9314000YW	8057	saremco print CROWNTEC A4	Ila	Q010205	16730	Saremco Dental AG	G1 055249 0010
++D9314000YW	8058	saremco print CROWNTEC C3	Ila	Q010205	16730	Saremco Dental AG	G1 055249 0010
++D9314000YW	8059	saremco print CROWNTEC C4	Ila	Q010205	16730	Saremco Dental AG	G1 055249 0010
++D9311000Y9	8060	els extra low shrinkage flow A3 syringe	Ila	Q01010103	35870	Saremco Dental AG	G1 055249 0010



Basic-UDI-DI	Article Number	Name of Medical Device	Class	EMDN Code	GMDN Code	Legal Manufacturer	Unique identification number of the certificate issued by a forementioned office
++D9314000YW	8062	saremco print DENTURETEC	IIa	Q01020699	16730	Saremco Dental AG	G1 055249 0010
++D9314000YW	8063	saremco print CROWNTEC A1	IIa	Q010205	16730	Saremco Dental AG	G1 055249 0010
++D9314000YW	8065	saremco print CROWNTEC B1	IIa	Q010205	16730	Saremco Dental AG	G1 055249 0010
++D9314000YW	8066	saremco print CROWNTEC SW	IIa	Q010205	16730	Saremco Dental AG	G1 055249 0010
++D9313000YP	8067	Zirconia Primer 5ml	IIa	Q01010102	62474	Saremco Dental AG	G1 055249 0010