

EG-Konformitätserklärung für Medizinprodukte
EC-Declaration of Conformity of medical devices

Nach Anhang II.3 der EG-Richtlinie über Medizinprodukte 93/42/EWG
According to annex II.3 of the directive for medical devices 93/42/EEC

Hersteller/Manufacturer: Coltène/Whaledent AG
Adresse/Address: Feldwiesenstrasse 20
CH-9450 Altstätten

Wir erklären hiermit, dass das Produkt
Herewith we declare that the product

Produktname klassifiziert nach Anhang IX
Name of product der Richtlinie 93/42/EWG
classified according to annex IX
directive 93/42/EEC

SwissFlex Discs **Klasse/class IIa**
Benannte Stelle CE 0123
Notified Body CE 0123

UMDNS / GMDNS codes: 16-201/35702

den einschlägigen Bestimmungen der nachstehenden Richtlinie
complies with the relevant regulations of the following directive

Richtlinie 93/42/EWG vom 14. Juni 1993 über Medizinprodukte
Directive 93/42/EEC of June 14, 1993 for medical devices

und deren Umsetzung in nationale Gesetze entspricht.
and with the national laws adopted by Member States.

Ausgabedatum/Date of issue
Altstätten, 2010-01-14



Silke Wallaschek

Name und Unterschrift des Befugten
Name and signature of authorized person

EG-Konformitätserklärung für Medizinprodukte
EC-Declaration of Conformity of medical devices

Nach Anhang I und VII der EG-Richtlinie über Medizinprodukte 93/42/EWG
According to annex I and VII of the directive for medical devices 93/42/EEC

Hersteller/Manufacturer: Coltène/Whaledent AG
Adresse/Address: Feldwiesenstrasse 20
CH-9450 Altstätten

Wir erklären hiermit, dass das Produkt
Herewith we declare that the product

Produktname klassifiziert nach Anhang IX
Name of product der Richtlinie 93/42/EWG
classified according to annex IX
directive 93/42/EEC

SwissFlex Strips Klasse/class **I**

UMDNS / GMDNS codes: 16-201/35702

den einschlägigen Bestimmungen der nachstehenden Richtlinie
complies with the relevant regulations of the following directive

Richtlinie 93/42/EWG vom 14. Juni 1993 über Medizinprodukte
Directive 93/42/EEC of June 14, 1993 for medical devices

und deren Umsetzung in nationale Gesetze entspricht.
and with the national laws adopted by Member States.

Ausgabedatum/Date of issue

Altstätten, 2010-01-14



Silke Wallaschek

Name und Unterschrift des Befugten
Name and signature of authorized person

The above mentioned declaration of conformity is exclusively under the responsibility of following the procedure relating to the EC Declaration of Conformity set out in Annex VII coupled with Annex V of Directive 93/42/EBC.

The product concerned has been manufactured under a quality management system according to Annex VII of Directive 93/42/EBC.

following the procedure relating to the EC Declaration of Conformity set out in Annex VIII coupled with Annex V of Directive 93/42/EBC.



The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EBC. It bears the mark

meet the provisions of Directive 93/42/EBC which apply to them.

UMDNS-Code: 15-590

We, the manufacturer, herewith declare that the products
Intra-oral Tips, Impression oral tips(Ratio 1:1, Ratio 1:4)
SIZE: Yellow 1:1,S; Purple 1:1,XL; Teal 1:1; Pink 1:1,M;
Blue 1:1 Long w/58mm stem,tapered;
Blue 1:1 Short w/taper end
Blue (orange inside) 1:4
Brown 1:1 Short, cement mixer
Brown 1:1 Core, build-up mixer
Brown 1:1 Long, Temp cement mixer

Shanghai Dochem Industries Co., Ltd.
Suite 705, No.7, FU LI Building, Lane 1306
Jiang Ning Road, Shanghai, China

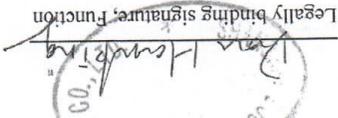
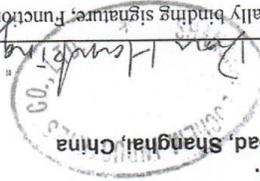
whose single authorized Representative:
Wellkang Ltd via Wellkang Tech Consulting
Suite B, 29 Harley Street LONDON W1G
9QR England, United Kingdom

EC Declaration of Conformity

Place, date

Shanghai, 25 May 2010

Legally binding signature; Function

Shanghai Dochem Industries Co., Ltd.
Suite 705, No.7, FU LI Building, Lane 1306 Jiang Ning Road, Shanghai, China

EC DECLARATION OF CONFORMITY
According to Annex VII of MDD 93/42/EEC

TF0200 060424

GC EUROPE N.V.
Research Park
Interleuvenlaan 13
B-3001 Leuven
Belgium

We ensure and declare under our sole responsibility that the products :

GC FUJI PLUS

GC FUJI PLUS CAPSULES

to which this declaration relates are in conformity with the following standards or other normative documents :

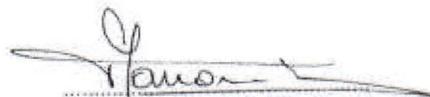
Company Standard AF-33-Q-301-3006 (1)

EN 1641 : 1996 - Dentistry - Medical Devices for Dentistry - Materials
(where applicable)

and meet the provisions of Council Directive 93/42/EEC concerning Medical Devices which apply to them, and is manufactured in accordance with the technical documentation.

This products is Class IIa according to annex IX of the Council Directive

Leuven, 26 APR. 2006
Date



P. Martouviez
Compliance and Quality Systems Manager
On behalf of GC EUROPE N.V.

Interleuvenlaan 13
B-3100 Leuven Belgium

tel: +32 16 39.80.60

BE 452.407.307
fax: +32 16.40.02.14

Vertimas iš anglų kalbos

GC Europe N.V.
European Head Office



EC ATITIKTIES DEKLARACIJA
Pagal MDD 93/42/EEC Priedą VII

TF0200 060424

GC EUROPE N.V.
Research Park
Interleuvenlaan 13
B-3001 Leuven
Belgija

Prisiimdami visą atsakomybę mes užtikriname ir paskelbiame, kad produktai:

GC FUJI PLUS

GC FUJI PLUS KAPSULĖS

su kuriomis yra susijusi ši deklaracija, atitinka šiuos standartus ar kitus normatyvinius dokumentus:

Įmonės Standartą AF-33-Q-301-3006 (1)

EN 1641 : 1996 - Odontologija. Medicinos priemonės dantims gydyti. Medžiagos
(kur šis standartas yra taikomas)

ir taip pat atitinka Tarybos Direktyvos 93/42/EEC nuostatas susijusias su Medicininiais įrenginiais ir yra gaminamas pagal techninę dokumentaciją.

Šio produkto klasė yra IIa – pagal Tarybos Direktyvos priedą IX.

Leuven, 2006 m., balandžio 26 d.
Data

/parašas/

P. Manouvriez
Atitikimo ir Kokybės sistemų direktorius
GC EUROPE N.V. Kompanijos vardu

Interleuvenlaan 13
B-3100 Leuven Belgija

Tel.: +32 16 39 80 60

BE 452 407 307
Faksas: +32 16 40 02 14

Vertė UAB "RIVYDOS" VERTIMŲ BIURAS
Žalgirio g. 90, 09303 Vilnius
Tel./faksas: (370 5) 273 05 87

Vertėjas susipažinęs su LR BK 235 straipsniu

Vertėjas

Laimonas Žalakevičius

2007 m.

Spalio mėn. 13 d.



Susinta 2
(D) lapai



Konformitätserklärung Declaration of Conformity

Wir/We

Heraeus Kulzer GmbH & Co. KG
41538 Dormagen

erklären in eigener Verantwortung, daß das Produkt
confirm in own responsibility, that the product

ALLIGAT

den grundlegenden Anforderungen der „Richtlinie 93/42/EWG des Rates vom
14. Juni 1993 über Medizinprodukte“ entspricht.
comply with the essential requirements of the „directive 93/42/EEC of June 14,
1993 concerning medical devices“.

Produkt/Product:

Alligat 24 x 453 g

No: 66001763

Dormagen 26. August 1999
Ort und Datum
Place and Date


Geschäftsführer HKKG
General manager
Dr. Roland Richter

kas iš vokiečių kalbos

Atitikties patvirtinimas

Heraeus Kulzer GmbH & Co. KG
41538 Dormagen,

prisiimdami sau atsakomybę patvirtiname, kad gaminyje

ALLIGAT

atitinka pagrindinius, „1993 m. birželio 14 d. Tarybos direktyvos 93/42/EEB reikalavimus dėl medicininių prietaisų“.

Gaminys:

Alligat24 x 543 g

Nr. 66001763

Dormagen, 1999 m. rugpjūčio 26 d.
Vieta ir data

/Parašas/
Įmonės vadovas
Dr. Roland Richter

/Antspaudas. Heraeus Kulzer GmbH & Co. KG, Grüner Weg 11, 63450 Hanau/

DECLARATION OF CONFORMANCE

Manufacturer: Tokuyama Dental Corporation
Address: 38-9, Taitou 1-Chome, Taitou-Ku, Tokyo, JAPAN

European representative: Tokuyama Dental Italy S.r.l.
Address: Via dell'Artigianato, 7, 36030 Montecchio Precalcio, Vicenza, Italy

Product name: TOKUYAMA IONOTITE F
Reference No.: RC04

Classification (MDD, AnnexIX): Class IIa

First Shipment Date: 9 February, 2006
First lot Number: see attached sheet 1

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer and the notified body.

DIRECTIVES and REGULATION

General applicable directive and regulation:
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC as amended by 2007/47/EC
Regulation concerning the Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH), 1907/2006/EC

Standards: see attached sheet 2

Notified Body: Notified Body Number 0120
SGS United Kingdom Ltd

Address: 202B Worle Parkway, Weston-super-Mare, BS22 6WA, UK

Certificate: JP12/040317 (Annex II MDD)

Place: 38-9, Taitou 1-Chome, Taitou-Ku, Tokyo, Japan
Date: 10 July, 2012

Signature


Makoto Sakamoto
Executive Managing Director

First Lot Number for kit:

	First Lot Number in EU market	First shipment date
TOKUYAMA IONOTITE F Kit	K331Z5T	9 February 2006
TOKUYAMA IONOTITE F Mini Kit	XK40156	22 May 2006

First Lot Number for refill:

		First Lot Number in EU market	First shipment date
TOKUYAMA	Powder	X00537	22 March 2007
IONOTITE F	Liquid	X16637	22 March 2007

Standards applied to this product are listed below.

Standard	Published year
EN ISO 10993-1	2009
EN ISO 10993-3	2009
EN ISO 10993-5	2009
EN ISO 10993-10	2010
EN ISO 10993-11	2009
EN ISO 10993-12	2009
EN ISO 10993-18	2009
EN ISO 13485	2003
EN ISO 14971	2009
EN 980	2008
EN 1041	2008
EN 1641	2009
EN ISO 7405	2008
ISO 15223-1	2007
JIS T 6611	2009

ATITIKTIES DEKLARACIJA

Gamintojas: „Tokuyama Dental Corporation“
Adresas: 38-9, Taitou 1-Chome, Taitou-ku, Tokijas, Japonija
Atstovas Europoje: „Tokuyama Dental Italy S.r.l.“
Adresas: Via dell'Artigianato 7, 36030 Montecchio Precalcio, Vicenza, Italija

Prekinis pavadinimas: TOKUYAMA IONOTITE F
Dokumento Nr.: RC04

Klasifikacija (pagal Medicinos
priedaisų direktyvos (MDD) IX priedą): Klasė IIa

Pirmojo partijos data: 2006 m. vasario 9 d.
Pirmos partijos numeris: žr. I priedą

Šia deklaracija patvirtiname, kad nurodyti gaminiai atitinka žemiau įvardintų EB Tarybos direktyvose ir standartuose nustatytus reikalavimus. Visi atitiktį patvirtinantys dokumentai saugomi gamintojo ir notifikuotosios įstaigos patalpose.

DIREKTYVOS IR TEISĖS AKTAI

Galiojančios direktyvos ir teisės aktai:
Medicinos prietaisų direktyva: TARYBOS DIREKTYVA 93/42/EEB ir ją iš dalies keičianti direktyva 2007/47/EB
Reglamentas Nr. 1907/2006 dėl cheminių medžiagų registracijos, įvertinimo, autorizacijos ir apribojimų (REACH)

Standartai: žr. 2 priedą

Notifikuotoji įstaiga: Notifikuotosios įstaigos numeris 0120
„SGS United Kingdom Ltd“

Adresas: 202B Worle Parkway, Weston super: Mare, BS22 6WA, JK

Sertifikatas: JP12/040317 (MDD, II priedas)

Vieta: 38-9, Taitou 1-Chome, Taitou-ku, Tokijas, Japonija

Data: 2012 m. liepos 10 d.

Parašas */parašas/*
Makoto Sakamoto
Generalinis direktorius

DENTKIST logotipas

265 Dangjeong-dong, Gunpo-si, Gyeonggi-do, 435-831, Koreja TEL.: + 82 31 458 3230/ FAX : + 82 31 458 2556/

ATTIKTIES DEKLARACIJA

PAGAL MEDICINOS PRIETAISU DIREKTYVA 93/42/ECC II PRIEDO 3 SKIRSNIS

Mes savo paciy atakomybe pavirtinime, kad šie produktai yra klasifikuojami pagal žemiau nurodytas Medicininę prietaisų klases, kurioms ši deklaracija ir yra taikoma, pagal atitkiną standartams EN ISO 9001:2008 sertifikato nr. SY6 002817 0001 ir EN ISO 13485:2003 + AC: 2007 sertifikato nr. SX 60026052 0001 ir CE 0197 sertifikato nr. HD 60026050 0001;

Gaminio pavadinimas: Dentkist, Inc.

Gaminio kilmės šalis: # 265 Dangjeong-dong, Gunpo-si, Gyeonggi-do, 435-831, Koreja

TEL.: + 82 31 458 3230/ FAX : + 82 31 458 2556

Atikties rūšis: Savarankiška deklaracija

1. Produkto modelis: Charmfi Plus
Produktio pavadinimas: Kompozicines atkuriamos medziagos, dantų, gydymos šviesa
Klasifikacija: IIa klase
2. Produkto modelis: Charmfi Flow
Produktio pavadinimas: Kompozicines atkuriamos medziagos, dantų, gydymos šviesa
Klasifikacija: IIa klase
3. Produkto modelis: Charmbond
Produktio pavadinimas: Lipni medziaga
Klasifikacija: IIa klase
4. Produkto modelis: CharmSeal
Produktio pavadinimas: Stiprinanti medziaga
Klasifikacija: IIa klase
5. Produkto modelis: CharmErich
Produktio pavadinimas: Dantų esdimo skyščiai
Klasifikacija: IIa klase
6. Produkto modelis: CharmSensy
Produktio pavadinimas: Nejautra
Produktio klase: IIa klase
7. Produkto modelis: Quicks
Produktio pavadinimas: Kompozicines atkuriamos medziagos, dantų, gydymos šviesa
Produktio klase: IIa klase
8. Produkto modelis: Quicks Flow
Produktio pavadinimas: Kompozicines atkuriamos medziagos, dantų, gydymos šviesa
Produktio klase: IIa klase
9. Produkto modelis: CharmCore
Produktio pavadinimas: Kompozicines atkuriamos medziagos, dantų, savarankiskai gydomos
Produktio klase: IIa klase
10. Produkto modelis: CharmFlex Heavy, Regular, Light, Puty
Produktio pavadinimas: Dantų ispandų medziagos
Produktio klase: IIa klase
11. Produkto modelis: CharmDam
Produktio pavadinimas: Kompozicines atkuriamos medziagos, dantų, gydymos šviesa
Produktio klase: IIa klase

2011 Sausio 17d.

Dentkist, Inc.

2013. 12. 30



Direktore Marija Danileviciute

KOPIJĄ TIKRA



APPROVAL
EC Directive 93/42/EEC Annex II, Article 3
Full Quality Assurance System
Medical Devices

Registration No.: HD 60026050 0001

Report No.: 13009222 001

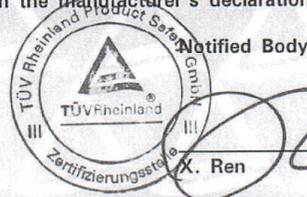
Manufacturer: DentKist, Inc.
#265 Dangeong-Dong, Gunpo-Si
435-831 Gyeonggi-Do
South Korea

Scope: Design and Development, Manufacture of Dental Materials
Products: see attachment

Date of Expiry: 15.05.2014

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Cologne, 30.07.2009



TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

Attachment to
Registration No.: HD 60026050 0001
Report No.: 13009222 001

Manufacturer: DentKist, Inc.
#265 Dangeong-Dong, Gunpo-Si
435-831 Gyeonggi-Do
South Korea

Scope:

Products:

- Light curing dental bonding agents/adhesives
- Light curing dental pit and fissure sealants
- Light curing dental composite resins
- Light curing dental temporary filling materials
- Light curing dental desensitizing agents
- Dental etching agents

Cologne, 30.07.2009



Certification Body

X. Ren

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Dokumentas 4/4

Priedas prie
Registracijos Nr.: HD 60037929 0001
Raporto Nr.: 21158216 003

Gamintojas: Heraeus Kulzer GmbH
Grüner Weg 11
63450 Hanau
Vokietija

Sudėtis: įtraukiamos vietovės:

Heraeus Kulzer GmbH
Alte Heerstraße, 41538 Dormagen, Vokietija

Odontologinių produktų kurimas / išradimas ir gamyba.
Platinimo centras.

Sertifikavo

Data 02.03.2011

Dipl. – Ing D. Meier

Vertė: Arūnas Juzėnas

Direktorė
Marija Danilevičiūtė



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Dokumentas 3/4

Priedas prie
Registracijos Nr.: HD 60037929 0001
Raporto Nr.: 21158216 003

Gamintojas: Heraeus Kulzer GmbH
Grüner Weg 11
63450 Hanau
Vokietija

Sudėtis: įtraukiamos vietovės:

Heraeus Kulzer GmbH
Quarztrasse 8, 63450 Hanau, Vokietija

Odontologinių produktų – taurių ir netaurių metalų odontologinių medžiagų CAD/CAM ir Selektivaus Lazerinio Lydimo Proceso – kurimas / išradimas ir gamyba.

Heraeus Kulzer GmbH
Philipp – Reis – Str. 8/13, 61273 Wehrheim, Vokietija

Odontologinių produktų kurimas / išradimas ir gamyba.

Heraeus Kulzer Austria GmbH
Nordbahnstraße 36, 1020 Wien, Austria

Taurių metalų odontologinių medžiagų gamyba ir odontologinių medžiagų platinimas.

Sertifikavo

Data 02.03.2011

Dipl. – Ing D. Meier

Vertė: Arūnas Juzėnas

Direktorė
Marija Danilavičiūtė



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Dokumentas 1/4

Priedas prie
Registracijos Nr.: HD 60037929 0001
Raporto Nr.: 21158216 003

Gamintojas: Heraeus Kulzer GmbH
Grüner Weg 11
63450 Hanau
Vokietija

Sudėtis: Produktai:

Polimerų pagrindo odontologinės medžiagos, vagelių / fisūrų padengimui
Polimerų pagrindo odontologinės medžiagos, plombavimui/ restauravimui
Odontologiniai poliruokliai
Odontologiniai implantai, kaulo atstatymo medžiagos
Odontologiniai cementai, polikarboksilatiniai
Odontologiniai cementai, conko fosfatiniai
Odontologiniai cementai, polimerų pagrindo
Odontologiniai deimantiniai gražteliai
Odontologinė šėdinimo želė / skystis
Polimerų pagrindo odontologinės medžiagos skirtos plokštelių bazei
Vainikėlių / tiltų medžiagos
Adhezyvai, dentino užpildai
Odontologinės adatos

Sertifikavo

Data 02.03.2011

Dipl. – Ing D. Meier

Vertė: Arūnas Juzėnas


Direktorė
Marija Danilevičiūtė
2013. 12. 30

PATVIRTINIMAS

EC Direktyva 93/42/EEC Priedas II, Straipsnis 3
Pilna Kokybės Užtikrinimo Sistema
Medicinos Prietaisai

Registracijos Nr.: HD 60037929 0001

Raporto Nr.: 21158216 003

Gamintojas: Heraeus Kulzer GmbH
Grüner Weg 11
63450 Hanau
Vokietija

Sudėtis: Odontologinių produktų (žiūrėkite pridedamus produktų ir priedų sąrašus) kurimas / išradimas ir gamyba.

Keičiamas patvirtinimas, kurio registracijos Nr.: HD 60014153 001

Galioja iki: 03.02.2016

Patvirtiname, kad aukščiau minėta įmonė sukūrė ir įdiegė kokybės valdymo sistemą. Direktyvos II Priedo, 3 Straipsnio reikalavimams atitinkama. Šis patvirtinimas yra nuolatinio tikrinimo subjektas, apsprendžiamas EC Direktyvos II Priedo, 3 Straipsnio, ir gali būti kompanijos naudojamas kartu su gamintojo atitikties deklaracija.

Pranešėjas

Data 02.03.2011

Dipl. – Ing D. Meier

TÜV Rheinland LGA Products GmbH – Tillystraße 2 – 90431 Nürnberg
Akredituota Zentralstelle der Länder für Sicherheitstechnik (ZLS) ir Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Nr. 0197 pagal EC Komisją

CE žymėjimas gali būti naudojamas jei atitinkama visoms svarbioms ir galiojančioms EC Direktyvoms.

Vertė: Arūnas Juzėnas

Direktorė
Marija Dankevičiūtė



Marija Dankevičiūtė
2013. 12. 30



APPROVAL
EC Directive 93/42/EEC Annex II, Article 3
Full Quality Assurance System
Medical Devices

Registration No.: HD 60037929 0001

Report No.: 21158216 003

Manufacturer: Heraeus Kulzer GmbH
Grüner Weg 11
63450 Hanau
Deutschland

Scope: Design/Development and Manufacture of dental products
(see attachment for products and additional sites included)
Replaces Approval, Registration No.: HD 60014153 0001

Date of Expiry: 03.02.2016

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body



Dipl.-Ing. D. Meier

Date 02.03.2011

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/4, Rev. 0

Attachment to
Registration No.: HD 60037929 0001
Report No.: 21158216 003

Manufacturer: Heraeus Kulzer GmbH
Grüner Weg 11
63450 Hanau
Deutschland

Scope:

Products:

- Dental material, pit/fissure sealing, polymer based
- Dental material, filling/ restorative, polymer-based
- Burnisher, dental
- Dental implant, bone reconstruction
- Cement, dental, polycarboxylate
- Cement, dental, zinc phosphate
- Cement, dental, polymer based
- Bur, dental, diamond
- Dental etching liquid/-gel
- Dental material, denture base, polymer based
- Crown/bridge material
- Adhesives, dentine
- Needles, dental

Date 02.03.2011



Dipl.-Ing. D. Meier



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/4, Rev. 0

Attachment to
Registration No.: HD 60037929 0001
Report No.: 21158216 003

Manufacturer: Heraeus Kulzer GmbH
Grüner Weg 11
63450 Hanau
Deutschland

Scope: Products:

- Crown/bridge, temporary
- Dental ceramic
- Dental alloy and -solders, noble
- Dental alloy and -solders, non-noble
- Attachments
- Electro plating baths for dental applications
- Precious metal pastes for dental applications

Date 02.03.2011

Certification Body

Dipl.-Ing. D. Meier



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 3/4, Rev. 0

Attachment to
Registration No.: HD 60037929 0001
Report No.: 21158216 003

Manufacturer: Heraeus Kulzer GmbH
Grüner Weg 11
63450 Hanau
Deutschland

Scope: Sites included:

Heraeus Kulzer GmbH
Quarzstrasse 8, 63450 Hanau, Germany

- Design/Development and Manufacture of dental products, CAD/CAM and Selective Laser Melting Process of precious and non-precious metal dental materials

Heraeus Kulzer GmbH
Philipp-Reis-Str. 8/13, 61273 Wehrheim, Germany

- Design/Development and Manufacture of dental materials

Heraeus Kulzer Austria GmbH
Nordbahnstraße 36, 1020 Wien, Austria

- Manufacture of precious metal dental materials and distribution of dental materials

Date 02.03.2011

Certification Body



Dipl.-Ing. D. Meier



Doc. 4/4, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: HD 60037929 0001
Report No.: 21158216 003

Manufacturer: Heraeus Kulzer GmbH
Grüner Weg 11
63450 Hanau
Deutschland

Scope: Sites included:
Heraeus Kulzer GmbH
Alte Heerstraße, 41538 Dormagen, Germany
- Design/Development and Manufacture of dental materials
and distribution center

Date 02.03.2011

Certification Body

Dipl.-Ing. D. Meier

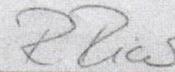
Konformitätserklärung / Declaration of Conformity Anhang / Annex: Artikelliste / List of Articles

Das Medizinprodukt /
The medical device
Versionsnummer/ Version number: **Prevision CEM**
2
Ersetzt Anhang vom/
Replaces Annex from: 2004-11-02

Artikelbezeichnung/ Article name	Artikelnummer/ Article number
PREVISION CEM TUB 1 X 37 G	66001540
PREVISION CEM TUB 4 X 37 G	66001541

Hanau, 2006-03-28
Ort, Datum / Place, date

Dr. Roland Richter
Geschäftsführer / General Manager
Heraeus Kulzer GmbH
Name und Funktion / Name and function



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Dokumentas 4/4

Priedas prie
Registracijos Nr.: HD 60037929 0001
Raporto Nr.: 21158216 003

Gamintojas: Heraeus Kulzer GmbH
Grüner Weg 11
63450 Hanau
Vokietija

Sudėtis: įtraukiamos vietovės:

Heraeus Kulzer GmbH
Alte Heerstraße, 41538 Dormagen, Vokietija

Odontologinių produktų kurimas / išradimas ir gamyba.
Platinimo centras.

Sertifikavo

Data 02.03.2011

Dipl. – Ing D. Meier

Vertė: Arūnas Juzėnas

Direktorė
Marija Danilevičiūtė



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Dokumentas 3/4

Priedas prie
Registracijos Nr.: HD 60037929 0001
Raporto Nr.: 21158216 003

Gamintojas: Heraeus Kulzer GmbH
Grüner Weg 11
63450 Hanau
Vokietija

Sudėtis: įtraukiamos vietovės:

Heraeus Kulzer GmbH
Quarztrasse 8, 63450 Hanau, Vokietija

Odontologinių produktų – taurių ir netaurių metalų odontologinių medžiagų CAD/CAM ir Selektivaus Lazerinio Lydimo Proceso – kurimas / išradimas ir gamyba.

Heraeus Kulzer GmbH
Philipp – Reis – Str. 8/13, 61273 Wehrheim, Vokietija

Odontologinių produktų kurimas / išradimas ir gamyba.

Heraeus Kulzer Austria GmbH
Nordbahnstraße 36, 1020 Wien, Austria

Taurių metalų odontologinių medžiagų gamyba ir odontologinių medžiagų platinimas.

Sertifikavo

Data 02.03.2011

Dipl. – Ing D. Meier

Vertė: Arūnas Juzėnas

Direktorė
Marija Danilevičiūtė



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Dokumentas 1/4

Priedas prie
Registracijos Nr.: HD 60037929 0001
Raporto Nr.: 21158216 003

Gamintojas: Heraeus Kulzer GmbH
Grüner Weg 11
63450 Hanau
Vokietija

Sudėtis: Produktai:

Polimerų pagrindo odontologinės medžiagos, vagelių / fisūrų padengimui
Polimerų pagrindo odontologinės medžiagos, plombavimui/ restauravimui
Odontologiniai poliruokliai
Odontologiniai implantai, kaulo atstatymo medžiagos
Odontologiniai cementai, polikarboksilatiniai
Odontologiniai cementai, conko fosfatiniai
Odontologiniai cementai, polimerų pagrindo
Odontologiniai deimantiniai gražteliai
Odontologinė šėdinimo želė / skystis
Polimerų pagrindo odontologinės medžiagos skirtos plokštelių bazei
Vainikėlių / tiltų medžiagos
Adhezyvai, dentino užpildai
Odontologinės adatos

Sertifikavo

Data 02.03.2011

Dipl. – Ing D. Meier

Vertė: Arūnas Juzėnas

LIETUVOS RESPUBLIKA
KOPIJOS TIKRA
2013.12.30
Direktorė
Marija Danilevičiūtė

PATVIRTINIMAS

EC Direktyva 93/42/EEC Priedas II, Straipsnis 3
Pilna Kokybės Užtikrinimo Sistema
Medicinos Prietaisai

Registracijos Nr.: HD 60037929 0001

Raporto Nr.: 21158216 003

Gamintojas: Heraeus Kulzer GmbH
Grüner Weg 11
63450 Hanau
Vokietija

Sudėtis: Odontologinių produktų (žiūrėkite pridedamus produktų ir priedų sąrašus) kurimas / išradimas ir gamyba.

Keičiamas patvirtinimas, kurio registracijos Nr.: HD 60014153 001

Galioja iki: 03.02.2016

Patvirtiname, kad aukščiau minėta įmonė sukūrė ir įdiegė kokybės valdymo sistemą. Direktyvos II Priedo, 3 Straipsnio reikalavimams atitinkama. Šis patvirtinimas yra nuolatinio tikrinimo subjektas, apsprendžiamas EC Direktyvos II Priedo, 3 Straipsnio, ir gali būti kompanijos naudojamas kartu su gamintojo atitikties deklaracija.

Pranešėjas

Data 02.03.2011

Dipl. – Ing D. Meier

TÜV Rheinland LGA Products GmbH – Tillystraße 2 – 90431 Nürnberg
Akredituota Zentralstelle der Länder für Sicherheitstechnik (ZLS) ir Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Nr. 0197 pagal EC Komisją

CE žymėjimas gali būti naudojamas jei atitinkama visoms svarbioms ir galiojančioms EC Direktyvoms.

Vertė: Arūnas Juzėnas

Direktorė
Marija Dambavičiūtė



komisja tikra
2013. 12. 30



APPROVAL
EC Directive 93/42/EEC Annex II, Article 3
Full Quality Assurance System
Medical Devices

Registration No.: HD 60037929 0001

Report No.: 21158216 003

Manufacturer: Heraeus Kulzer GmbH
Grüner Weg 11
63450 Hanau
Deutschland

Scope: Design/Development and Manufacture of dental products
(see attachment for products and additional sites included)
Replaces Approval, Registration No.: HD 60014153 0001

Date of Expiry: 03.02.2016

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body



Date 02.03.2011

Dipl.-Ing. D. Meier

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. **0197** to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/4, Rev. 0

Attachment to
Registration No.: HD 60037929 0001
Report No.: 21158216 003

Manufacturer: Heraeus Kulzer GmbH
Grüner Weg 11
63450 Hanau
Deutschland

Scope:

Products:

- Dental material, pit/fissure sealing, polymer based
- Dental material, filling/ restorative, polymer-based
- Burnisher, dental
- Dental implant, bone reconstruction
- Cement, dental, polycarboxylate
- Cement, dental, zinc phosphate
- Cement, dental, polymer based
- Bur, dental, diamond
- Dental etching liquid/-gel
- Dental material, denture base, polymer based
- Crown/bridge material
- Adhesives, dentine
- Needles, dental

Date 02.03.2011



Dipl.-Ing. D. Meier



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/4, Rev. 0

Attachment to
Registration No.: HD 60037929 0001
Report No.: 21158216 003

Manufacturer: Heraeus Kulzer GmbH
Grüner Weg 11
63450 Hanau
Deutschland

Scope: Products:

- Crown/bridge, temporary
- Dental ceramic
- Dental alloy and -solders, noble
- Dental alloy and -solders, non-noble
- Attachments
- Electro plating baths for dental applications
- Precious metal pastes for dental applications

Date 02.03.2011

Certification Body



Dipl.-Ing. D. Meier



Doc. 3/4, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to
Registration No.: HD 60037929 0001
Report No.: 21158216 003

Manufacturer: **Heraeus Kulzer GmbH**
Grüner Weg 11
63450 Hanau
Deutschland

Scope: Sites included:

Heraeus Kulzer GmbH
Quarzstrasse 8, 63450 Hanau, Germany

- Design/Development and Manufacture of dental products, CAD/CAM and Selective Laser Melting Process of precious and non-precious metal dental materials

Heraeus Kulzer GmbH
Philipp-Reis-Str. 8/13, 61273 Wehrheim, Germany

- Design/Development and Manufacture of dental materials

Heraeus Kulzer Austria GmbH
Nordbahnstraße 36, 1020 Wien, Austria

- Manufacture of precious metal dental materials and distribution of dental materials

Date 02.03.2011

Certification Body

Dipl.-Ing. D. Meier



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 4/4, Rev. 0

Attachment to
Registration No.: HD 60037929 0001
Report No.: 21158216 003

Manufacturer: **Heraeus Kulzer GmbH**
Grüner Weg 11
63450 Hanau
Deutschland

Scope: Sites included:
Heraeus Kulzer GmbH
Alte Heerstraße, 41538 Dormagen, Germany
- Design/Development and Manufacture of dental materials
and distribution center

Date 02.03.2011

Certification Body

Dipl.-Ing. D. Meier



265 Dangjeong-dong, Gunpo-si, Gyeonggi-do, 435-831, Korea TEL : + 82 31 458 3230 / FAX : + 82 31 458 2556 /

DECLARATION OF CONFORMITY
TO MEDICAL DEVICES DIRECTIVE 93/42/EEC Annex II, Article 3

We here with declare in our own responsibility that following products have been classified as below-mentioned

Medical Devices classes, to which this declaration relates in conformity with the standards of EN ISO 9001:2008

certificate no. : SY 60028174 0001 and EN ISO 13485:2003 + AC: 2007 certificate no. : SX 60026052 0001, and CE 0197

certificate no. : HD 60026050 0001;

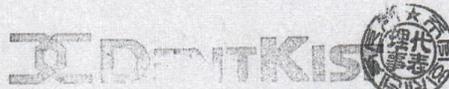
© Manufacturer's name : Dentkist, Inc.

© Country of origin of the manufacturer : # 265 Dangjeong-dong, Gunpo-si, Gyeonggi-do, 435-831, Korea.

TEL : +82 31 458 3230 FAX : +82 31 458 2556

© Conformity route : Self Declaration

1. Model of product : CharmFil Plus
Name of product : Composite Restorative Material Kits, Dental, Light-Cured
Classification : Class IIa
2. Model of product: CharmFil Flow
Name of product : Composite Restorative Material Kits, Dental, Light-Cured)
Classification : Class IIa
3. Model of product: CharmBond
Name of product : Adhesives
Classification : Class IIa,
4. Model of product: CharmSeal
Name of product : Restorative Materials, Dental, Unfilled
Classification : Class IIa,
5. Model of product: CharmEtch
Name of product : Dental Etching Liquids
Classification : Class IIa,
6. Model of product: CharmSensy
Name of product : Desensitizers
Classification : Class IIa,
7. Model of product: Quicks
Name of product : Composite Restorative Material Kits, Dental, Light-Cured
Classification : Class IIa,
8. Model of product: Quicks Flow
Name of product : Composite Restorative Material Kits, Dental, Light-Cured
Classification : Class IIa,
9. Model of product: CharmCore
Name of product : Composite Restorative Materials, Dental, Self-Cured
Classification : Class IIa,
10. Model of product: CharmFlex Heavy, Regular, Light, Putty
Name of product : Dental Impression Materials
Classification : Class I
11. Model of product: CharmDam
Name of product : Composite Restorative Material Kits, Dental, Light-Cured
Classification : Class I,



#265 Dangjeong-dong, Gunpo-si, Gyeonggi-do, 435-831, Korea

Tel : +82-31-458-3230(H.O), +82-31-458-2555(S.D)

Fax : +82-31-458-2556

17th JAN, 2011

DentKist, Inc.

DENTKIST logotipas

265 Dangeong-dong, Gunpo-si, Gyeonggi-do, 435-831, Korėja TEL: + 82 31 458 3230/ FAX : + 82 31 458 2556/

ATITIKTIES DEKLARACIJA

PAGAL MEDICINOS PRIETAISŲ DIREKTYVĄ 93/42/EEC II PRIEDO 3 SKIRSNIS

Mes savo pačių atsakomybe patvirtiname, kad šie produktai yra klasifikuojami pagal žemiau nurodytas Medicininių prietaisų klases, kurioms ši deklaracija ir yra taikoma, pagal atitikimą standartams EN ISO 9001:2008 sertifikato nr. SY6 002817 0001 ir EN ISO 13485:2003 + AC: 2007 sertifikato nr. SX 60026052 0001 ir CE 0197 sertifikato nr. HD 60026050 0001;

Gamintojo pavadinimas: **Dentkist, Inc.**

Gamintojo kilmės šalis: # 265 Dangeong-dong, Gunpo-si, Gyeonggi-do, 435-831, Korėja

TEL: + 82 31 458 3230/ FAX : + 82 31 458 2556

Atitikties rūšis: **Savarankiška deklaracija**

1. Produkto modelis: Charmfil Plus
Produkto pavadinimas: Kompozicinės atkuriamos medžiagos, dantų, gydymo šviesa
Klasifikacija: IIa klasė
2. Produkto modelis: Charmfil Flow
Produkto pavadinimas: Kompozicinės atkuriamos medžiagos, dantų, gydymo šviesa
Klasifikacija: IIa klasė
3. Produkto modelis: Charmbond
Produkto pavadinimas: Lipni medžiaga
Klasifikacija: IIa klasė
4. Produkto modelis: CharmSeal
Produkto pavadinimas: Stiprinanti medžiaga
Klasifikacija: IIa klasė
5. Produkto modelis: CharmEtch
Produkto pavadinimas: Dantų ėsdinimo skyščiiai
Klasifikacija: IIa klasė
6. Produkto modelis: CharmSensy
Produkto pavadinimas: Nejautra
Produkto klasė: IIa klasė
7. Produkto modelis: Quicks
Produkto pavadinimas: Kompozicinės atkuriamos medžiagos, dantų, gydymo šviesa
Produkto klasė: IIa klasė
8. Produkto modelis: Quicks Flow
Produkto pavadinimas: Kompozicinės atkuriamos medžiagos, dantų, gydymo šviesa
Produkto klasė: IIa klasė
9. Produkto modelis: CharmCore
Produkto pavadinimas: Kompozicinės atkuriamos medžiagos, dantų, savarankiškai gydomos
Produkto klasė: IIa klasė
10. Produkto modelis: CharmFlex Heavy, Regular, Light, Putty
Produkto pavadinimas: Dantų įspaudų medžiagos
Produkto klasė: IIa klasė
11. Produkto modelis: CharmDam
Produkto pavadinimas: Kompozicinės atkuriamos medžiagos, dantų, gydymo šviesa
Produkto klasė: IIa klasė

Dentkist antspaudas

2011 Sausio 17d.

/parašas/

DentKist, Inc.

EG-KONFORMITÄTSBESCHEINIGUNG

entsprechend Anhang VII der Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über
Medizinprodukte

EC ATTESTATION OF CONFORMITY

according to annex VII of the Council Directive 93/42/EEC of June 14th, 1993 concerning
medical devices

Wir: Coltène/Whaledent GmbH + Co. KG Raiffeisenstr. 30 D-89129 Langenau Germany	We: Coltène/Whaledent GmbH + Co. KG Raiffeisenstr. 30 D-89129 Langenau Germany
erklären in alleiniger Verantwortung, daß die Produkte: Bezeichnung: Abdecktücher Artikulationspapier Artikulationsseide Endodontikinstrumente Endodontikinstrument-Organisierer Handschuhe Kältespray Klemmpinzetten Kofferdam Kofferdam Klammern Kofferdam Klammerzange Kofferdam Lochzange Kofferdam Rahmen Kompressionshütchen Kopfschutztaschen Marker Mulltupfer Mundschutz Occlusionsfolie und Zubehör Patientenumhänge Polierstreifen Retraktionsfäden und Zubehör Schaumstoffpellets Schlauchüberzüge Schleifstreifen Shimstock-Folie Stahlmatrizenband Stahlseparierstreifen Wattekügelchen Watterollen Wurzelkanal-Tips	declare under our sole responsibility that the products: Name: Covers Articulating paper Articulating silk Endodontic instruments Endodontic organizer Gloves Cold spray Clamping tweezers Dental dam Dental dam clamps Dental dam clamp forceps Dental dam punch Dental dam frames Compression caps Headrest covers Markers Gauze swabs Face masks Occlusion foils and accessories Patient bibs Polishing strips Retraction cords and accessories Foam plastic pellets Sleeves for tubes Abrasive strips Shimstock-foil Steel matrix bands Steel separating strips Cotton pellets Cotton rolls Root canal tips

EG-Konformitätsbescheinigung, Anhang VII
EC-Attestation of conformity, annex VII

erstellt am/issued: 22.11.13/MIL
ersetzt Version vom/replaces version of: 18.07.13/BW

den einschlägigen Bestimmungen des Anhangs VII der Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte entspricht.	<i>meets the provisions of annex VII of the Council Directive 93/42/EEC of June 14th, 1993 concerning medical devices which apply to it.</i>
Diese EG-Konformitätsbescheinigung ist gültig bis 30.07.2018.	<i>This EC-Attestation of conformity is valid until 30.07.2018.</i>

Langenau, 22.11.13

B. Wellbrock
.....
Barbara Wellbrock
Director QM/QC/RA

EG-Konformitätsbescheinigung, Anhang VII
EC-Attestation of conformity, annex VII

erstellt am/issued: 22.11.13/MIL
ersetzt Version vom/replaces version of: 18.07.13/BW

EG-KONFORMITÄTSERKLÄRUNG

entsprechend Anhang II der Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über
Medizinprodukte

EC ATTESTATION OF CONFORMITY

according to annex II of the Council Directive 93/42/EEC of June 14th, 1993 concerning
medical devices

<p>Wir: Coltene/Whaledent GmbH + Co. KG Raiffeisenstr. 30 D-89129 Langenau</p>	<p>We: Coltene/Whaledent GmbH + Co. KG Raiffeisenstr. 30 D-89129 Langenau</p>
<p>erklären in alleiniger Verantwortung, daß die Produkte:</p> <p>Bezeichnung:</p> <ul style="list-style-type: none"> Wurzelkanalfüllungsmaterialien Wurzelkanalbürsten Papierspitzen Absaugkanülen Sterile Mulltupfer Chirurgisches Nahtmaterial (nicht resorbierbar) Arzneimittelhaltige Retraktionsfäden Arzneimittelhaltige Gelatineschwämmchen Verbandmittel mit Jodoform Tamponadebinde Wurzelkanalfeilen Dentale rotierende Handstücke mit Bohrantrieb 	<p>declare under our sole responsibility that the products:</p> <p>Name:</p> <ul style="list-style-type: none"> Root canal filling materials Root canal brushes Paper points Aspirator tips Sterile gauze swabs Surgical sutures (non-resorbable) Medicated retraction cords Medicated gelatin sponges Bandage with Iodoform Tamponade bandage Root canal files Dental rotary handpieces with engine
<p>den einschlägigen Bestimmungen des Anhangs II der Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte entspricht.</p>	<p>meets the provisions of annex II of the Council Directive 93/42/EEC of June 14th, 1993 concerning medical devices which apply to it.</p>
<p>Benannte Stelle: medical device certification GmbH Kriegerstraße 6 70191 Stuttgart Germany</p> <p>Nummer der Benannten Stelle: 0483</p>	<p>Notified Body: medical device certification GmbH Kriegerstraße 6 70191 Stuttgart Germany</p> <p>Number of the Notified Body: 0483</p>
<p>Diese EG-Konformitätsbescheinigung ist gültig bis 30.07.2018.</p>	<p>This EC-Attestation of conformity is valid until 30.07.2018.</p>

Langenau, 18.07.13

B. Wellbrock
.....
Barbara Wellbrock
Director QM/QC/RA

EG-Konformitätsbescheinigung, Anhang II
EC-Attestation of conformity, annex II

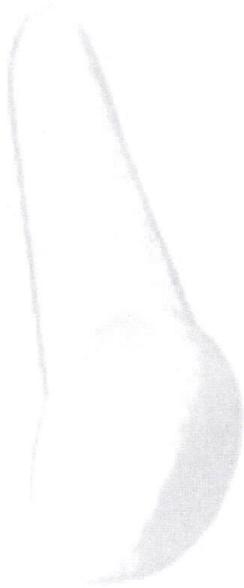
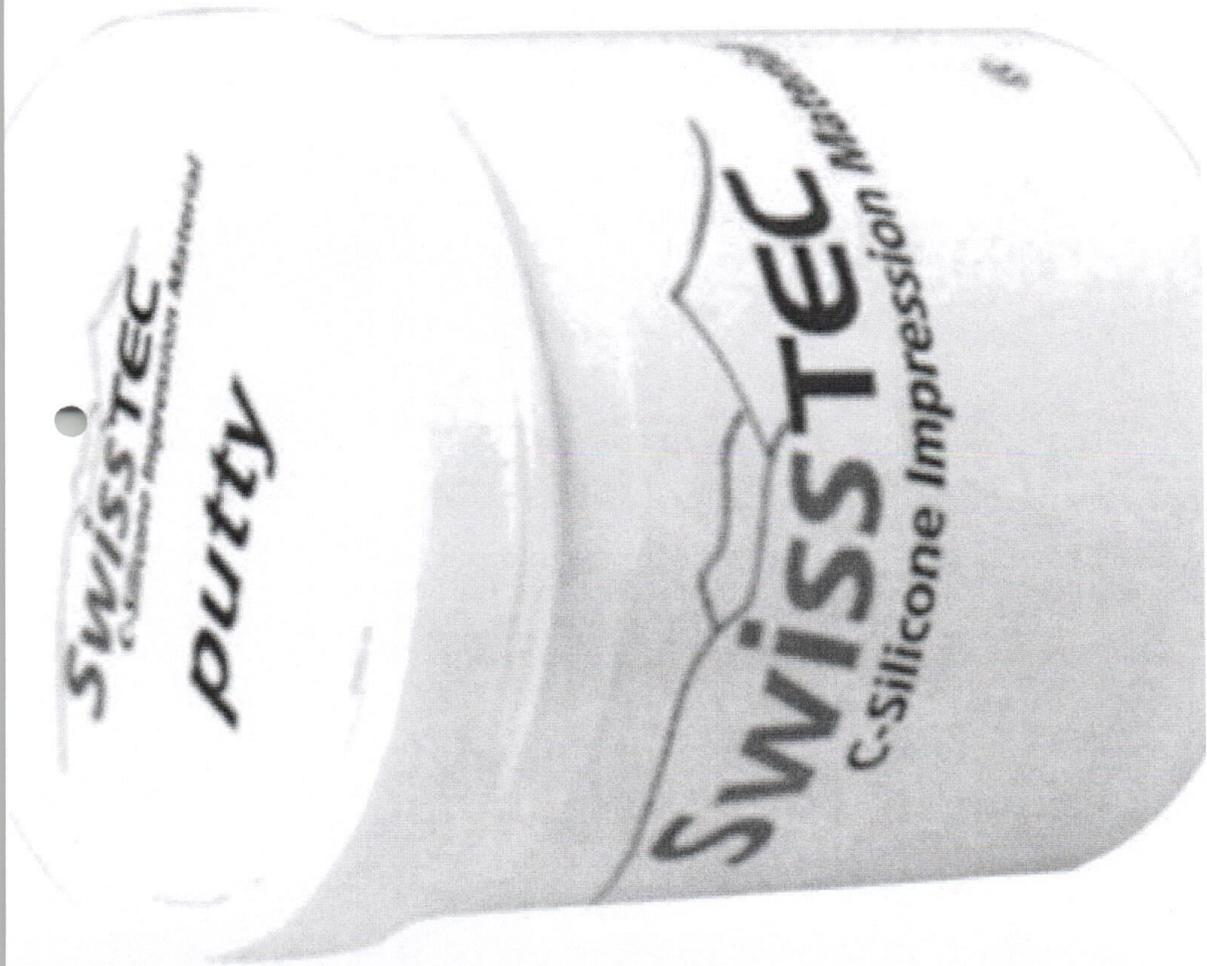
erstellt am/issued: 18.07.13/BW
ersetzt Version vom/replaces version of: 01.08.08/BW



coltene
whaledent

light body

SWISSTEC
C-Silicone Impression Material





coltene
whaledent

Universal Activator

SWISSTEC
C-Silicone Impression Material

Estecem

Dvigubo kietėjimo dervinis cementas

Skirtas vainikėlių, tiltų, įklotų, užklotų iš stiklo, porceliano, keramikos, aliuminio, metalo, cementavimui

Porceliano pataisoms

Visoms keramikos pataisoms

Venyryų cementavimui

Stiklo ir metalo kaiščiams cementuoti

Techninė informacija:

Stiprumas su emaliu 33,1Mpa

Stiprumas su dentinu 29,2 Gpa

Lankstumo stiprumas 158Mpa

Sluoksnio sluoksnis 8mikrometrai

Sugeriamumas vandeniui 12,0mikro g/mm²

Estecem 9,4g švirškštai tipo automix.

Spalvos:

- Skaidri
- Universali
- Ruda
- Balta opakinė

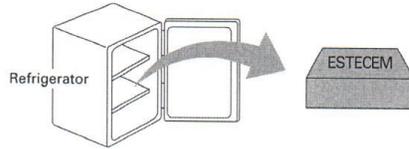
Naudojamas su adhesine sistema Estelink A ir B

Ryšio stiprumui naudojamas praimeris A ir B

ESTECEM Clinical Procedure Guide



The PASTE, ESTELINK or TOKUYAMA UNIVERSAL PRIMER should be brought to room temperature before using.



After removing from the refrigerator, allow the product to sit for 20 minutes or until it reaches room temperature.

If the syringe is not brought up to room temperature, you will find it difficult to squeeze out the paste.
If the bottle is not brought up to room temperature, you will find it difficult to dispense one drop of liquid.

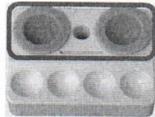
5254301411

Outline

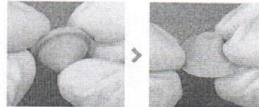


Point

How to dispense of ESTELINK

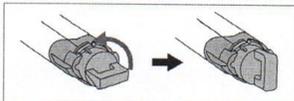


Use the rubber dispensing well provided when dispensing and mixing of ESTELINK. If ESTELINK is not dispensed into the rubber dispensing it may be difficult to remove the cured ESTELINK from dispensing well. The cured ESTELINK can be removed by inverting the rubber.



After mixing, the color of ESTELINK changes gradually based on the reaction of the catalyst of ESTELINK, this is normal and does not indicate a problem with ESTELINK.

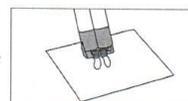
How to attach the mixing tip



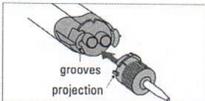
Turn the cap 1/4 of a turn counterclockwise to align the projections on the cap with the grooves in the syringe



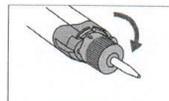
Holding the base of the cap, remove the cap by twisting and pressing downward



Before each use, squeeze out a small quantity of PASTE A and B, making sure equal amounts are being dispensed through the two outlets of the syringe

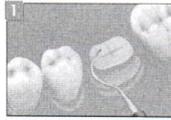


Attach a mixing tip to the syringe aligning the projections on the mixing tip with the grooves in the syringe as closely as possible



Turn the mixing tip 1/4 of a turn clockwise to lock it in place

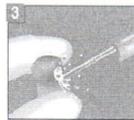
Clinical Procedure Guide for ESTECEM Read instruction before operation



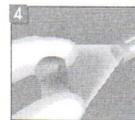
Tooth Preparation
Remove contamination from the tooth surface such as plaque, temporary cement residue, oil from materials to test crown fit, oil mist from a hand-piece, saliva, blood and exudate fluids by brushing with flour pumice, ultrasonic scaling or cleaning the surface of the tooth with alcohol. Thoroughly rinse and dry the surface.



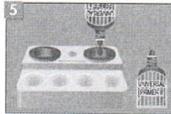
Restoration Preparation
Follow the procedure shown below, depending on the material to be restored.
1) Ceramics other than Porcelain, and Composite materials
Roughen the interior of the restoration by sandblasting (0.1 to 0.2MPa), air abrasion or grinding with a diamond bur using a slow speed to prepare the surface for adhesion.
2) Porcelain
DO NOT roughen the surface. Prepare the interior of the restoration, providing a clean and fresh surface for adhesion.
3) Metal restorations
Roughen the area by sandblasting (0.3 to 0.5MPa), air abrasion or grinding with a diamond bur using a slow speed to prepare the surface for adhesion.



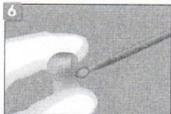
Thoroughly rinse the surface



Dry the surface



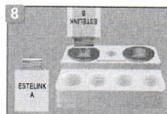
Restoration Pretreatment with the TOKUYAMA UNIVERSAL PRIMER
Dispense one drop each of TOKUYAMA UNIVERSAL PRIMER A and B into the dispensing well and mix.



Apply the mixed primer on the surface to be bonded and wait 10 seconds.



Apply mild air to the surface.



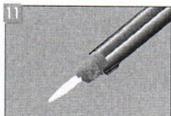
Tooth Pretreatment with the ESTELINK
Dispense one drop of ESTELINK BOND A and BOND B into the dispensing well and mix.
*Complete the application within 1 minute after dispensing.



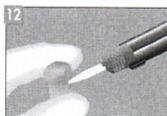
Apply the mixed ESTELINK on the surface to be bonded and wait 10 seconds.



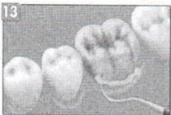
Apply mild air continuously to the surface until the runny ESTELINK stays in the same position without any movement, then strong air to the surface.



Cementation and Final Bonding
Attach a mixing tip to the syringe according to "How to attach the mixing tip".



Apply the mixed PASTE to the surface of the restoration and place the restoration on the tooth with firm pressure.



Removal of excess PASTE
● When using the light-cure method:
Light-cure the excess PASTE with a dental curing light for 2 to 4 seconds and remove the gel state of the excess PASTE.
● When using the self-cure method:
Remove the gel state of the excess PASTE within 1 to 3.5 minutes after seating.



Final PASTE hardening by light curing
● In case of translucent restoration materials such as ceramics:
Irradiate the light to the applied PASTE on the seated restoration for 20 seconds or more.
● In case of non translucent restoration materials such as metal:
Light-cure along margins for 20 seconds or more, then allow the PASTE to set for 8 minutes.
*If light curing is not enough, there is a possibility of poor adhesiveness.