

EC Certificate

mdc medical device certification GmbH

Notified Body 0483
herewith certifies that

DETAX GmbH & Co. KG
Carl-Zeiss-Straße 4
76275 Ettlingen
Germany

for the scope

dental products, otoplastic products
(see attachment)

has introduced and applies a

Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system
meets all requirements according to

Annex II – excluding Section 4
of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2020-04-02
Valid until	2024-05-26
Registration no.	D1002700043
Report no.	P20-00377-171147
Stuttgart	2020-04-02




Head of Certification Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-246.10.06

Attachment of the certificate

No. D1002700043

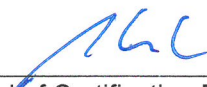
Date 2020-04-02

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Product category	Product	Class
dental moldings	freeform® (plast, fixgel) freeprint® splint E-Splint SOLFLEX med freeprint® ortho Flemmingprint ortho Twinprint ortho/splint Ultraprint-Dental Ortho UV Solflex ortho freeform® bond freeform® coat pico-splint star freeprint® denture Solflex denture Ultraprint-Dental Denture UV	Ila
dental cements	Drala® Phosphatzement Drala® Polycarboxylatzement Fermin, Detaferm® Clinicem Temp II tempolink® (single, clear) Anclacem temp dextalink implantlink® semi (classic, forte, Xray) Anclacem implant tginplaCem tginplaCem F	Ila
epithesis material	GINGIVAMOLL®	Ila
resins for the fabrication of otoplastics	silicone material (bioplast, earflex®, detax softwear®) silicone laquer (impression laquer, dip coat, express coat, frosty coat, micropor, super coat, softwear coat) composite (OTO LP, luxaprint® shellac, luxaprint® shellac color, luxaprint® 3D shell, luxaprint® 3D mould, luxaprint SL, freeprint® mould)	Ila



mdc medical device certification GmbH
 Kriegerstraße 6
 D-70191 Stuttgart, Germany
 Phone: +49-(0)711-253597-0
 Fax: +49-(0)711-253597-10
 Internet: <http://www.mdc-ce.de>


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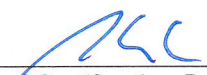
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Product category	Product	Class
resins for the fabrication of otoplastics	KREOS medical audio, freeprint® shell) Autopolymerisat (acrylon®) resins (adaptmold®) adaptmold® optimum) luxaprint® softseal Primer luxaprint® softseal luxaprint® flex luxaprint® flex coat medicalprint	Ila
materials for the manufacturing of temporary crowns and bridges	tempofit® (duomix, premium, regular) tg tempolux dextatemp smartbond® smartrepair® smartrepair® rosa Lukafix tempofit® finish tempofit® semi freeprint® temp Flemmingprint temp Twinprint Testeneer-temp Ultraprint-Dental Temp UV Solflex prov	Ila
composite-based fissure sealant, light curing	smartseal® & loc smartseal® & loc F	Ila
one-component material, light curing	tempofill® 2 inlay	Ila
cavity cleaning liquid	Cavidex®	Ila
protective lacquer for root dentine	smartseal® cervi	Ila




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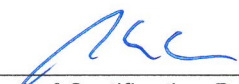
Date 2020-04-02

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Product category	Product	Class
permanently soft denture relining materials	Permaliner Molloplast® B Primo Lustrol mollosil® (with adhesive) mollosil® plus (with primer and polish) Anclasil rebase Rebasil® +2 Proclinc Expert Soft Relining automix Proclinc Expert Soft Relining handmix	Ila



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