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Nur zur elektronischen Verbreitung

EU Quality Management System Certificate

We hereby certify the company

DETAX GmbH
Carl-Zeiss-Straße 4
76275 Ettlingen
Germany

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment.

An audit by mdc has proven that this quality management system meets the following requirements:

Annex IX – Chapter I (Quality Management System)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate from mdc medical device certification GmbH (Notified Body 0483) consists of 10 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from	2024-03-22	Registration No.	D1002700058
Valid until	2028-07-31	Report No.	P23-00305-295649

Stuttgart, 2024-03-22

Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-098

Devices:

Dentures, Partial:
freeprint denture
Primeprint Denture
Solflex denture
Ultraprint-Dental Denture

Risk class: IIa

Restorative Materials, Dental, Crown and Bridge:
Flemmingprint temp
freeprint temp
Primeprint temp
Solflex prov
Twinprint Testeneer/Temp
Ultraprint-Dental Temp

Risk class: IIa

Composite for the fabrication of otoplastics:
e3D.M01
e3D.S01
freeprint mould
freeprint shell
Luxaprint 3D
Luxaprint SL
medicalprint
Solflex med

Risk class: IIa

Dental Splinting Materials:
Flemmingprint ortho
freeprint splint
freeprint ortho
Primeprint Guide
Primeprint Splint
SHERAprint - ortho plus
Solflex med 2.0
Solflex ortho
Twinprint Ortho/Splint
Ultraprint-Dental Ortho

Risk class: IIa

Dental Impression Materials, Silicone Rubber:
Anclasil hydrofluid fast
Anclasil hydrofluid regular
Anclasil hydroheavy
Anclasil hydroputty
Anclasil oclu
Anclasil oneputty
Anclasil onewash
Durcisseur pate
Detaseal antilock
Detaseal bite
Detaseal function
Detaseal hydroflow heavy
Detaseal hydroflow lite fast
Detaseal hydroflow lite regular
Detaseal hydroflow mono
Detaseal hydroflow mono Jumbo
Detaseal hydroflow putty
Detaseal hydroflow putty Jumbo
Detaseal hydroflow soft² putty
Detaseal hydroflow Xlite fast
Detaseal hydroflow Xlite regular
Dexta 10
Dexta 12
Dextaplast
easy tech heavy
easy tech lite fast pink
easy tech lite regular pink
easy tech putty hard
easy tech putty heavy
easy tech putty soft
Exact Bite
Exact Heavybody
Exact Lightbody light Fast
Exact Lightbody light Regular
Exact Lightbody medium Fast
Exact Lightbody medium Regular
Exact Mono
Exact Putty
Exact Putty Fast
Exact Putty Regular
Exagel cat.
exaplast Putty
exasoft Wash
glassbite
greenbite apple
greenbite colour
hydro C Activator
hydro C putty
hydro C wash

Katalysator für Sta-Seal,f,Silone
Katalysator Paste
Katalysator Silaplast
Katalysator Silasoft
milkbite
monoprint supra
occlusil +2
occlusil couleur
onetime perfect Jumbo
onetime perfect putty
onetime perfect wash
orangebite
Plurabite color
Reaktol
silaplast Futur
silaplast Futur A
silasoft Futur A
silasoft direct
silasoft normal
silasoft special
silone
sta-seal f
sta-seal

Risk class: IIa

Denture Reliners, Soft:
Anclasil rebase
Molloplast B
Mollosil plus
Mollosil
Permaliner
Proclinic Expert cartucho
Proclinic Expert tubos
rebasil +2

Risk class: IIa

Adhesives, Liquid:
Mollosil Adhäsiv
Mollosil plus Primer
Primo
Proclinic Expert adhesive cartucho
Proclinic Expert adhesive tubos
rebasil +2 apprêt

Risk class: IIa

Silicone lacquer for smoothing and sealing, dental:
Lustrol
Mollosil plus Politur

Risk class: IIa

Composite lacquer for smoothing and sealing, Audio:
Luxaprint flex coat
Luxaprint shellac
Luxaprint shellac color

Risk class: IIa

Ear Impression Materials, Silicone Rubber:
addition futur
addition junior
addition optimum
addition protect
addition rapid
addition spectra
addition supra
addition ultra
A-Zoft blau
Bachmaier oto soft
Bachmaier soft IT
blue eco audio
cat futur
Catalyseur OTOCIL
Catalyst paste futur Puresil
Catalyst paste Steramould
classic futur
Cotral pâte empreinte
detax addition
Detax flextime
Earsil
green eco
HL FLOW
HL SOFT
HL MIX
HL SPEED
egger A
egger A/soft
eggerA/I
egger A/II
egger A/ITE
egger A/rapidPRO
egger A/rapidSWITCH
egger C/II
Härter für egger C/II

OTO addition
OTO Puresil ll
OTOCIL
otolin inject
otolin manuell
pink mix
pink putty
Pluggerz heavy rapid
Pluggerz light
Pluggerz medium rapid
Protasil
Protasil Pate
PureSil
PureSil Pro
Steramould Plus
szilikon alapú

Risk class: IIa

Silicone materials for the fabrication of otoplastics:
bioplast
Comfoor glow in the dark
detax softwear 2.0
earflex
egger flex/AB

Risk class: IIa

Silicone lacquer for smoothing and sealing of silicone materials:
Abdrucklack
dip coat
express coat
frosty coat
Lack L
Lack L nano
Lack opaco
Lack signo
microporlack
softwear coat
super coat

Risk class: IIa

Restorative Materials, Dental, Crown and Bridge:
dextatemp
tempofit duomix
tempofit premium
tempofit regular

Risk class: IIa

Accessory kit, Restorative Materials, Dental, Crown and Bridge with Nano:
Lukafix
smartrepair
smartrepair rosa

Risk class: IIa

Accessory kit, Restorative Materials, Dental, Crown and Bridge:
Lukafix Bonder
smartbond

Risk class: IIa

Accessory kit, Restorative Materials, Dental, Crown and Bridge:
tempofit finish

Risk class: IIa

Restorative Materials, Dental, Crown and Bridge, implantable:
tempofit semi

Risk class: IIa

Cement, dental, other:
Anclacem implant
implantlink semi classic
implantlink semi forte
implantlink semi Xray

Risk class: IIa

Cement, dental, other:
Anclacem temp
dextalink
tempolink clear

Risk class: IIa

Cement, dental, other:
tempolink single

Risk class: IIa

Cement, dental, other:
Fermin
Clinicem Temp II
Detaferm

Risk class: IIa

Restorative Materials, Dental, Crown and Bridge 3D, implantable:
freeprint crown

Risk class: IIa

Dental Splinting Materials:
freeform fixgel
freeform plast
freeform plast Starterset
Pico-splint star Modelliergel

Risk class: IIa

Cavity Varnish:
freeform coat
Pico-splint star Glanzlack

Risk class: IIa

Adhesives, Liquid:
freeform bond
Pico-splint star Bonder

Risk class: IIa

Restorative Materials, dental, unfilled:
LUNOS clear
LUNOS Fissurenversiegler opaque
smartseal & loc F
smartseal & loc

Risk class: IIa

Restorative Materials, dental, other:
tempofill 2 inlay

Risk class: IIa

Cavity Varnish:
smartseal cervi

Risk class: IIa

Composite for the fabrication of otoplastics:
egger LP/H
egger LP/H Modellierpaste
egger LP/HS
LP/H
LP/H Modellierpaste
LP/S

Risk class: IIa

Composite lacquer for smoothing and sealing:
egger LP/H Lack antibac
egger LP/H Lack
egger LP/W Lack
LP/H Lack antibak
LP/H Lack
LP/W Lack

Risk class: IIa

Synthetic material for fabrication of otoplastics:
adaptmold
adaptmold optimum
THERMOtec
THERMOtec optimum

Risk class: IIa

Dentures, partial, Accessories:
freeprint tryin

Risk class: IIa

Composite for the fabrication of otoplastics:
acrylon

Risk class: IIa

Dental Splinting Materials:
freeprint splintmaster taff
freeprint splintmaster flex
Primeprint Splint SF
Primeprint Splint ST
SHERAprint-sprint flex
SHERAprint-splint taff

Risk class: IIa

The certificate is based on the previous certificates

- D1002700046 vom 2020-10-15
- D1002700049 vom 2021-09-27
- D1002700050 vom 2021-12-16
- D1002700053 vom 2022-04-29
- D1002700054 vom 2022-10-27

- D1002700057 dated 2023-08-01 with the following changes:
  Supplemented by product variants in confirmed product groups:
  Ear Impression Materials, Silicone Rubber: HL FLOW, HL SOFT, HL MIX, HL SPEED, egger A, egger A/soft, eggerA/I, egger A/II, egger A/ITE, egger A/rapidPRO, egger A/rapidSWITCH, eggerC/II, Härter für egger C/II, otolin inject, otolin manuell
  Silicone materials for the fabrication of otoplastics: egger flex /AB
  Composite for the fabrication of otoplastics: e3D.M01, e3D.S01
  Accessory kit, Restorative Materials, Dental, Crown and Bridge with Nano: Smartrepair rosa, Lukafix
  Dental Splinting Materials: SHERAprint – ortho plus
  Dental Splinting Materials: freeform fixgel
  Composite lacquer for smoothing and sealing: egger LP/H Lack antibac, egger LP/H Lack, egger LP/W Lack
  Composite for the fabrication of otoplastics: egger LP/H, egger LP/H Modellierpaste, egger LP/HS
  Silicone lacquer for smoothing and sealing of silicone materials: Lack L, Lack L nano, Lack opaco, Lack signo
  Changed: Article name is changed from Lunos opaque to Lunos Fissurenversiegler opaque