

Für/ For

DeguDent GmbH
Rodenbacher Chaussee 4
63457 Hanau
Germany

erklären wir in alleiniger Verantwortung, dass/ we declare having sole responsibility that

Dokumentennummer/
Document Number: Q-04-KE-14-0021

Revisionsindex/
Revision Index: 11

Produktnummer/
Product number

Produktbezeichnung

Product names

Produktnummer/ Product number	Produktbezeichnung	Product names
5368900501	Pulver	Powder
5360900503	Dentsply Universal NE-Bonder, Paste, 4 ml	Dentsply Universal NP-Bonder, Paste, 4 ml
5360900505	Duceram Kiss NE-Bonder 20g	Duceram Kiss NE-Bonder 20g
5360900523	Duceram Kiss Intensiv Pulveropaker Orange 20 g	Duceram Kiss Intensiv Powder Opaque Orange 20 g
5360901003	Duceram Kiss Opaker OA 1 20 g	Duceram Kiss Opaque OA 1 20 g
5360901005	Duceram Kiss Opaker OA 1 75 g	Duceram Kiss Opaque OA 1 75 g
5360901013	Duceram Kiss Opaker OA 2 20 g	Duceram Kiss Opaque OA 2 20 g
5360901015	Duceram Kiss Opaker OA 2 75 g	Duceram Kiss Opaque OA 2 75 g
5360901023	Duceram Kiss Opaker OA 3 20 g	Duceram Kiss Opaque OA 3 20 g
5360901025	Duceram Kiss Opaker OA 3 75 g	Duceram Kiss Opaque OA 3 75 g
5360901033	Duceram Kiss Opaker OA 3,5 20 g	Duceram Kiss Opaque OA 3,5 20 g
5360901035	Duceram Kiss Opaker OA 3,5 75 g	Duceram Kiss Opaque OA 3,5 75 g
5360901043	Duceram Kiss Opaker OA 4 20 g	Duceram Kiss Opaque OA 4 20 g
5360901045	Duceram Kiss Opaker OA 4 75 g	Duceram Kiss Opaque OA 4 75 g
5360901053	Duceram Kiss Opaker OB 1 20 g	Duceram Kiss Opaque OB 1 20 g
5360901055	Duceram Kiss Opaker OB 1 75 g	Duceram Kiss Opaque OB 1 75 g
5360901063	Duceram Kiss Opaker OB 2 20 g	Duceram Kiss Opaque OB 2 20 g
5360901065	Duceram Kiss Opaker OB 2 75 g	Duceram Kiss Opaque OB 2 75 g
5360901073	Duceram Kiss Opaker OB 3 20 g	Duceram Kiss Opaque OB 3 20 g
5360901075	Duceram Kiss Opaker OB 3 75 g	Duceram Kiss Opaque OB 3 75 g
5360901083	Duceram Kiss Opaker OB 4 20 g	Duceram Kiss Opaque OB 4 20 g
5360901085	Duceram Kiss Opaker OB 4 75 g	Duceram Kiss Opaque OB 4 75 g
5360901093	Duceram Kiss Opaker OC 1 20 g	Duceram Kiss Opaque OC 1 20 g
5360901095	Duceram Kiss Opaker OC 1 75 g	Duceram Kiss Opaque OC 1 75 g
5360901103	Duceram Kiss Opaker OC 2 20 g	Duceram Kiss Opaque OC 2 20 g
5360901105	Duceram Kiss Opaker OC 2 75 g	Duceram Kiss Opaque OC 2 75 g
5360901113	Duceram Kiss Opaker OC 3 20 g	Duceram Kiss Opaque OC 3 20 g
5360901115	Duceram Kiss Opaker OC 3 75 g	Duceram Kiss Opaque OC 3 75 g
5360901123	Duceram Kiss Opaker OC 4 20 g	Duceram Kiss Opaque OC 4 20 g
5360901125	Duceram Kiss Opaker OC 4 75 g	Duceram Kiss Opaque OC 4 75 g
5360901133	Duceram Kiss Opaker OD 2 20 g	Duceram Kiss Opaque OD 2 20 g
5360901135	Duceram Kiss Opaker OD 2 75 g	Duceram Kiss Opaque OD 2 75 g
5360901143	Duceram Kiss Opaker OD 3 20 g	Duceram Kiss Opaque OD 3 20 g
5360901145	Duceram Kiss Opaker OD 3 75 g	Duceram Kiss Opaque OD 3 75 g
5360901153	Duceram Kiss Opaker OD 4 20 g	Duceram Kiss Opaque OD 4 20 g
5360901155	Duceram Kiss Opaker OD 4 75 g	Duceram Kiss Opaque OD 4 75 g
5360901203	Duceram Kiss Opaker Bleach 20 g	Duceram Kiss Opaque Bleach 20 g
5360901205	Duceram Kiss Opaker Bleach 75 g	Duceram Kiss Opaque Bleach 75 g
5360909003	Duceram Kiss Gum-Opaker 20 g	Duceram Kiss Gum-Opaque 20 g
5360911003	Duceram Kiss Dentin DA 1 20 g	Duceram Kiss Dentine DA 1 20 g

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5360911005	Duceram Kiss Dentin DA 1 75 g	Duceram Kiss Dentine DA 1 75 g
5360911013	Duceram Kiss Dentin DA 2 20 g	Duceram Kiss Dentine DA 2 20 g
5360911015	Duceram Kiss Dentin DA 2 75 g	Duceram Kiss Dentine DA 2 75 g
5360911023	Duceram Kiss Dentin DA 3 20 g	Duceram Kiss Dentine DA 3 20 g
5360911025	Duceram Kiss Dentin DA 3 75 g	Duceram Kiss Dentine DA 3 75 g
5360911033	Duceram Kiss Dentin DA 3,5 20 g	Duceram Kiss Dentine DA 3,5 20 g
5360911035	Duceram Kiss Dentin DA 3,5 75 g	Duceram Kiss Dentine DA 3,5 75 g
5360911043	Duceram Kiss Dentin DA 4 20 g	Duceram Kiss Dentine DA 4 20 g
5360911045	Duceram Kiss Dentin DA 4 75 g	Duceram Kiss Dentine DA 4 75 g
5360911053	Duceram Kiss Dentin DB 1 20 g	Duceram Kiss Dentine DB 1 20 g
5360911055	Duceram Kiss Dentin DB 1 75 g	Duceram Kiss Dentine DB 1 75 g
5360911063	Duceram Kiss Dentin DB 2 20 g	Duceram Kiss Dentine DB 2 20 g
5360911065	Duceram Kiss Dentin DB 2 75 g	Duceram Kiss Dentine DB 2 75 g
5360911073	Duceram Kiss Dentin DB 3 20 g	Duceram Kiss Dentine DB 3 20 g
5360911075	Duceram Kiss Dentin DB 3 75 g	Duceram Kiss Dentine DB 3 75 g
5360911083	Duceram Kiss Dentin DB 4 20 g	Duceram Kiss Dentine DB 4 20 g
5360911085	Duceram Kiss Dentin DB 4 75 g	Duceram Kiss Dentine DB 4 75 g
5360911093	Duceram Kiss Dentin DC 1 20 g	Duceram Kiss Dentine DC 1 20 g
5360911095	Duceram Kiss Dentin DC 1 75 g	Duceram Kiss Dentine DC 1 75 g
5360911103	Duceram Kiss Dentin DC 2 20 g	Duceram Kiss Dentine DC 2 20 g
5360911105	Duceram Kiss Dentin DC 2 75 g	Duceram Kiss Dentine DC 2 75 g
5360911113	Duceram Kiss Dentin DC 3 20 g	Duceram Kiss Dentine DC 3 20 g
5360911115	Duceram Kiss Dentin DC 3 75 g	Duceram Kiss Dentine DC 3 75 g
5360911123	Duceram Kiss Dentin DC 4 20 g	Duceram Kiss Dentine DC 4 20 g
5360911125	Duceram Kiss Dentin DC 4 75 g	Duceram Kiss Dentine DC 4 75 g
5360911133	Duceram Kiss Dentin DD 2 20 g	Duceram Kiss Dentine DD 2 20 g
5360911135	Duceram Kiss Dentin DD 2 75 g	Duceram Kiss Dentine DD 2 75 g
5360911143	Duceram Kiss Dentin DD 3 20 g	Duceram Kiss Dentine DD 3 20 g
5360911145	Duceram Kiss Dentin DD 3 75 g	Duceram Kiss Dentine DD 3 75 g
5360911153	Duceram Kiss Dentin DD 4 20 g	Duceram Kiss Dentine DD 4 20 g
5360911155	Duceram Kiss Dentin DD 4 75 g	Duceram Kiss Dentine DD 4 75 g
5360911203	Duceram Kiss Bleach-Dentin 20 g	Duceram Kiss Bleach-Dentine 20 g
5360911205	Duceram Kiss Bleach-Dentin 75 g	Duceram Kiss Bleach-Dentine 75 g
5360911223	Duceram Kiss Dentin Bleach BL1 20g	Duceram Kiss Dentine Bleach BL1 20g
5360911233	Duceram Kiss Dentin Bleach BL2 20g	Duceram Kiss Dentine Bleach BL2 20g
5360911243	Duceram Kiss Dentin Bleach BL3 20g	Duceram Kiss Dentine Bleach BL3 20g
5360911253	Duceram Kiss Dentin Bleach BL4 20g	Duceram Kiss Dentine Bleach BL4 20g
5360911193	Duceram Kiss Action-i Dentin Butter 20g	Duceram Kiss Action-i Dentine Butter 20g
5360911193	Duceram Kiss Action-i Dentin Chocolat 20g	Duceram Kiss Action-i Dentine Chocolat 20g
53609111923	Duceram Kiss Action-i Dentin Corn 20g	Duceram Kiss Action-i Dentine Corn 20g
53609111933	Duceram Kiss Action-i Dentin Creme 20g	Duceram Kiss Action-i Dentine Creme 20g
53609111943	Duceram Kiss Action-i Dentin Honey 20g	Duceram Kiss Action-i Dentine Honey 20g
53609111953	Duceram Kiss Action-i Dentin Lavender 20g	Duceram Kiss Action-i Dentine Lavender 20g
53609111963	Duceram Kiss Action-i Dentin Marble 20g	Duceram Kiss Action-i Dentine Marble 20g
5360915103	Duceram Kiss Transpa Red 20g	Duceram Kiss Transpa Red 20g
5360915113	Duceram Kiss Gray Inside 20g	Duceram Kiss Gray Inside 20g
5360917003	Duceram Kiss Flu Inside 1 20 g	Duceram Kiss Flu Inside 1 20 g
5360917053	Duceram Kiss Flu Inside 2 20 g	Duceram Kiss Flu Inside 2 20 g
5360919003	Duceram Kiss Gum Dentin 1 20 g	Duceram Kiss Gum Dentine 1 20 g
5360919013	Duceram Kiss Gum Dentin 2 20 g	Duceram Kiss Gum Dentine 2 20 g
5360919023	Duceram Kiss Gum Dentin 3 20 g	Duceram Kiss Gum Dentine 3 20 g
5360919033	Duceram Kiss Gum Dentin 4 20 g	Duceram Kiss Gum Dentine 4 20 g
5360921503	Duceram Kiss Schneide S01 20 g	Duceram Kiss Incisal S01 20 g
5360921505	Duceram Kiss Schneide S01 75 g	Duceram Kiss Incisal S01 75 g
5360921513	Duceram Kiss Schneide S02 20 g	Duceram Kiss Incisal S02 20 g
5360921515	Duceram Kiss Schneide S02 75 g	Duceram Kiss Incisal S02 75 g
5360921523	Duceram Kiss Schneide S03 20 g	Duceram Kiss Incisal S03 20 g
5360921525	Duceram Kiss Schneide S03 75 g	Duceram Kiss Incisal S03 75 g
5360921533	Duceram Kiss Schneide S04 20 g	Duceram Kiss Incisal S04 20 g
5360921535	Duceram Kiss Schneide S04 75 g	Duceram Kiss Incisal S04 75 g
5360921543	Duceram Kiss Schneide S05 20 g	Duceram Kiss Incisal S05 20 g
5360921545	Duceram Kiss Schneide S05 75 g	Duceram Kiss Incisal S05 75 g

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5360921553	Duceram Kiss Schneide S06 20 g	Duceram Kiss Incisal S06 20 g
5360921555	Duceram Kiss Schneide S06 75 g	Duceram Kiss Incisal S06 75 g
5360921623	Duceram Kiss Schneide Bleach BL1/BL2 20g	Duceram Kiss Incisal Bleach BL1/BL2 20g
5360921633	Duceram Kiss Schneide Bleach BL3/BL4 20g	Duceram Kiss Incisal Bleach BL3/BL4 20g
5360923003	Duceram Kiss Transpa Clear 20 g	Duceram Kiss Transpa Clear 20 g
5360923005	Duceram Kiss Transpa Clear 75 g	Duceram Kiss Transpa Clear 75 g
5360923013	Duceram Kiss White Surface WS 20 g	Duceram Kiss White Surface WS 20 g
5360923023	Duceram Kiss Stand By S By 20 g	Duceram Kiss Stand By S By 20 g
5360923025	Duceram Kiss Stand By S By 75 g	Duceram Kiss Stand By S By 75 g
5360927003	Duceram Kiss Opal Effekt Sunrise 20 g	Duceram Kiss Opal Effekt Sunrise 20 g
5360927005	Duceram Kiss Opal Effekt Sunrise 75 g	Duceram Kiss Opal Effekt Sunrise 75 g
5360927023	Duceram Kiss Opal Effekt Sunset 20 g	Duceram Kiss Opal Effekt Sunset 20 g
5360927025	Duceram Kiss Opal Effekt Sunset 75 g	Duceram Kiss Opal Effekt Sunset 75 g
5360927033	Duceram Kiss Opal Effekt Sky 20 g	Duceram Kiss Opal Effekt Sky 20 g
5360927035	Duceram Kiss Opal Effekt Sky 75 g	Duceram Kiss Opal Effekt Sky 75 g
5360927043	Duceram Kiss Opal Effekt Ocean 20 g	Duceram Kiss Opal Effekt Ocean 20 g
5360927045	Duceram Kiss Opal Effekt Ocean 75 g	Duceram Kiss Opal Effekt Ocean 75 g
5360927053	Duceram Kiss Opal Effekt Fog 20 g	Duceram Kiss Opal Effekt Fog 20 g
5360927055	Duceram Kiss Opal Effekt Fog 75 g	Duceram Kiss Opal Effekt Fog 75 g
5360927503	Duceram Kiss Opalschneide 1 20 g	Duceram Kiss Opal Incisal 1, 20 g
5360927505	Duceram Kiss Opalschneide 1 75 g	Duceram Kiss Opal Incisal 1 75 g
5360927513	Duceram Kiss Opalschneide 2 20 g	Duceram Kiss Opal Incisal 2 20 g
5360927515	Duceram Kiss Opalschneide 2 75 g	Duceram Kiss Opal Incisal 2 75 g
5360937003	Duceram Kiss Korrekturmasse / 20 g	Duceram Kiss Add-on Porcelain 20 g
5360937005	Duceram Kiss Korrekturmasse / 75 g	Duceram Kiss Add-on Porcelain 75 g
5360941003	Duceram Kiss Schultermasse SM 1 20 g	Duceram Kiss Shoulder Porcelain SM1 20 g
5360941013	Duceram Kiss Schultermasse SM 2 20 g	Duceram Kiss Shoulder Porcelain SM2 20 g
5360941023	Duceram Kiss Schultermasse SM 3 20 g	Duceram Kiss Shoulder Porcelain SM3 20 g
5360941033	Duceram Kiss Schultermasse SM 4 20 g	Duceram Kiss Shoulder Porcelain SM4 20 g
5360941043	Duceram Kiss Schultermasse SM 5 20 g	Duceram Kiss Shoulder Porcelain SM5 20 g
5360941053	Duceram Kiss Finalschultermasse 1 20 g	Duceram Kiss Final Shoulder Porcelain FSM1 20 g
5360941063	Duceram Kiss Finalschultermasse 2 20 g	Duceram Kiss Final Shoulder Porcelain FSM2 20 g
5360941073	Duceram Kiss Finalschultermasse 3 20 g	Duceram Kiss Final Shoulder Porcelain FSM3 20 g
5360941083	Duceram Kiss Finalschultermasse 4 20 g	Duceram Kiss Final Shoulder Porcelain FSM4 20 g
5360941093	Duceram Kiss Finalschultermasse 5 20 g	Duceram Kiss Final Shoulder Porcelain FSM5 20 g
5360941223	Duceram Kiss Schultermasse Bleach 20g	Duceram Kiss Shoulder Porcelain Bleach 20g
5360955003	Duceram Kiss Power Chroma PC 1 20 g	Duceram Kiss Power Chroma PC 1 20 g
5360955013	Duceram Kiss Power Chroma PC 2 20 g	Duceram Kiss Power Chroma PC 2 20 g
5360955015	Duceram Kiss Power Chroma PC 2 75 g	Duceram Kiss Power Chroma PC 2 75 g
5360955023	Duceram Kiss Power Chroma PC 3 20 g	Duceram Kiss Power Chroma PC 3 20 g
5360955025	Duceram Kiss Power Chroma PC 3 75 g	Duceram Kiss Power Chroma PC 3 75 g
5360955033	Duceram Kiss Power Chroma PC 4 20 g	Duceram Kiss Power Chroma PC 4 20 g
5360955035	Duceram Kiss Power Chroma PC 4 75 g	Duceram Kiss Power Chroma PC 4 75 g
5360955043	Duceram Kiss Power Chroma PC 5 20 g	Duceram Kiss Power Chroma PC 5 20 g
5360955045	Duceram Kiss Power Chroma PC 5 75 g	Duceram Kiss Power Chroma PC 5 75 g
5360955053	Duceram Kiss Power Chroma PC 6 20 g	Duceram Kiss Power Chroma PC 6 20 g
Pasten		Paste
5360900500	Duceram Kiss Pastenbonder 3ml	Duceram Kiss Paste Bonder 3ml
5360901200	Duceram Kiss Bleach Pasten Opaker 3 ml	Duceram Kiss Bleach Paste Opaque 3 ml
5360901220	Duceram Kiss Pastenopaker Bleach BL1/ BL2 3ml	Duceram Kiss Paste Opaque Bleach BL1/ BL2 3ml
5360901230	Duceram Kiss Pastenopaker Bleach BL3/ BL4 3ml	Duceram Kiss Paste Opaque Bleach BL3/ BL4 3ml
5360903000	Duceram Kiss Pasten-Opaker PO A 1 / 3ml	Duceram Kiss Paste Opaque PO A1 / 3ml
5360903010	Duceram Kiss Pasten-Opaker PO A2 / 3ml	Duceram Kiss Paste Opaque PO A2 / 3ml
5360903020	Duceram Kiss Pasten-Opaker PO A3 / 3ml	Duceram Kiss Paste Opaque PO A3 / 3ml
5360903030	Duceram Kiss Pasten-Opaker PO A3,5 / 3ml	Duceram Kiss Paste Opaque PO A3,5 / 3ml
5360903040	Duceram Kiss Pasten-Opaker PO A4 / 3ml	Duceram Kiss Paste Opaque PO A4 / 3ml
5360903050	Duceram Kiss Pasten-Opaker PO B1 / 3ml	Duceram Kiss Paste Opaque PO B1 / 3ml
5360903060	Duceram Kiss Pasten-Opaker PO B2 / 3ml	Duceram Kiss Paste Opaque PO B2 / 3ml
5360903070	Duceram Kiss Pasten-Opaker PO B3 / 3ml	Duceram Kiss Paste Opaque PO B3 / 3ml
5360903080	Duceram Kiss Pasten-Opaker PO B4 / 3ml	Duceram Kiss Paste Opaque PO B4 / 3ml
5360903090	Duceram Kiss Pasten-Opaker PO C1 / 3ml	Duceram Kiss Paste Opaque PO C1 / 3ml
5360903100	Duceram Kiss Pasten-Opaker PO C2 / 3ml	Duceram Kiss Paste Opaque PO C2 / 3ml

5360903110	Duceram Kiss Pasten-Opaker PO C3 / 3ml	Duceram Kiss Paste Opaque PO C3 / 3ml
5360903120	Duceram Kiss Pasten-Opaker PO C4 / 3ml	Duceram Kiss Paste Opaque PO C4 / 3ml
5360903130	Duceram Kiss Pasten-Opaker PO D2 / 3ml	Duceram Kiss Paste Opaque PO D2 / 3ml
5360903140	Duceram Kiss Pasten-Opaker PO D3 / 3ml	Duceram Kiss Paste Opaque PO D3 / 3ml
5360903150	Duceram Kiss Pasten-Opaker PO D4 / 3ml	Duceram Kiss Paste Opaque PO D4 / 3ml
5360903160	Duceram Kiss Neutralpaste 3 ml	Duceram Kiss Neutral Paste 3ml
5360903200	Duceram Kiss Gum Pasten-Opaker 3ml	Duceram Kiss Gum Paste Opaque 3ml
5360903560	Duceram Kiss Pasten-Opaker P IO Orange / 3ml	Duceram Kiss Paste Opaque P IO Orange / 3ml
Sets		Kits
5360990131	Duceram Kiss Vollsortiment mit Pastenopaker	Duceram Kiss Complete Assortment with Paste opaque
5360990132	Duceram Kiss Vollsortiment mit Pulveropaker	Duceram Kiss Complete Assortment with Powder opaque
5360990141	Duceram Kiss Starter Set	Duceram Kiss Starter Kit
5360990151	Duceram Kiss Test Set	Duceram Kiss Test Kit
5360990161	Duceram Kiss Artist Add-on Kit	Duceram Kiss Artist Add-on Kit
5360990191	Duceram Kiss Bleach Shades Set	Duceram Kiss Bleach Shades Kit
5360990231	Duceram Kiss Basic Set	Duceram Kiss Basic Set
5360990241	Duceram Kiss Starter Set	Duceram Kiss Starter Set
5360990251	Duceram Kiss Aesthetic Set	Duceram Kiss Aesthetic Set

Medizinprodukteklasse/ medical device class IIa

mit den Bestimmungen der nachstehenden Richtlinie(n) übereinstimmt/
complies with the requirements of the following guideline(s)

EG-Richtlinie 93/42/EWG vom 14. Juni 1993 über Medizinprodukte/
Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

Benannte Stelle/ Notified Body: 0124/DEKRA Certification GmbH, Handwerkstraße 15, D-70565 Stuttgart)

Es wurde ein Konformitätsbewertungsverfahren gemäß Anhang II, ohne Abschnitt 4 der Richtlinie 93/42/EWG durchgeführt./
A conformity assessment according to Annex II, without Point 4 of the directive 93/42/EEC was conducted.

Die Gültigkeit dieser Erklärung ist durch das Ablaufdatum der von der benannten Stelle ausgestellten Bescheinigung begrenzt./
The validity of this declaration is limited by the expiration date of the certificate issued by the Notified Body.

Dr. Völk 17. FEB. 2020

Hanau,

Datum, Name, Unterschrift Forschung und Entwicklung/
date, name, signature Research and Development

Dr. Frank-Josef Grau

12.02.2020

Datum, Name, Unterschrift Qualitätsmanagement/
date, name, signature Quality Management