

Die MK-dent GmbH erklärt in alleiniger Verantwortung, dass die hier aufgeführten Produkte Medizinprodukte im Sinne des Artikels 1 der EG-Richtlinie 93/42/EWG über Medizinprodukte sind und den grundlegenden Anforderungen aus Anhang I der gleichen Richtlinie entsprechen.

Die Konformität wurde mittels des hier genannten Konformitätsbewertungsverfahrens festgestellt, die entsprechenden Bestimmungen aus der Richtlinie und den harmonisierten Normen wurden eingehalten.

The MK-dent GmbH hereby declares under its sole responsibility that all products listed here are medical devices in terms of Article 1 of the EU directive 93/42/EEC on medical devices and that they fulfill the relevant essential requirements of Annex I of the same directive.

Conformity was established by means of the conformity assessment procedure mentioned here, by complying with the corresponding provisions of the Directive and the harmonized standards.

Hersteller <i>Manufacturer:</i>	MK-dent GmbH Marie-Curie-Str. 2 22941 Bargteheide Deutschland <i>Germany</i>
Produktbeschreibung <i>Product description:</i>	Druckluftbetriebene Turbinenhandstücke zum Antrieb zahnärztlicher rotierender Instrumente mit FG-Schaft sowie gerade und abgewinkelte Handstücke <i>Air pressure operated turbine handpieces for driving dental rotating instruments with FG-shaft as well as straight and contra angled handpieces</i>
Produktvarianten <i>Product variants:</i>	siehe nächste Seite <i>see next page</i>
Konformitätsbewertungsverfahren <i>Conformity assessment procedure:</i>	Richtlinie 93/42/EWG; Anhang V <i>Directive 93/42/EEC; Annex V</i>
Klassifizierung <i>Classification:</i>	Klasse IIa <i>Class IIa</i>
Regel <i>Rule:</i>	Anhang IX: Regel 9 <i>Annex IX: Rule 9</i>
Benannte Stelle <i>Notified Body:</i>	TÜV SÜD Product Service GmbH Ridlerstr. 65, 80339 München
Kennnummer <i>Identification number:</i>	0123
Gültig bis <i>expiry date:</i>	26.05.2024

Bargteheide, 01.03.2021


M. Kleene
Geschäftsführer | *General Manager*

Artikel Item	Beschreibung Description
HB12	BASIC LINE High Speed Handpiece
HB14	BASIC LINE High Speed Handpiece
HB15L	BASIC LINE High Speed Handpiece with Light
HB16L	BASIC LINE High Speed Handpiece with Light
HB21K	BASIC LINE High Speed Handpiece
HB21KL	BASIC LINE High Speed Handpiece with Light
HB23K	BASIC LINE High Speed Handpiece
HB23KL	BASIC LINE High Speed Handpiece with Light
HC20K	CLASSIC LINE High Speed Handpiece
HC20KL	CLASSIC LINE High Speed Handpiece with Light
HC21K	CLASSIC LINE High Speed Handpiece
HC21KL	CLASSIC LINE High Speed Handpiece with Light
HC22K	CLASSIC LINE High Speed Handpiece
HC22KL	CLASSIC LINE High Speed Handpiece with Light
HC8021K	PRIME LINE High Speed Handpiece
HE11	ECO LINE High Speed Handpiece
HE12	ECO LINE High Speed Handpiece
HE14	ECO LINE High Speed Handpiece
HE15L	ECO LINE High Speed Handpiece with Light
HE16L	ECO LINE High Speed Handpiece with Light
HE17	ECO LINE High Speed Handpiece
HE17B	ECO LINE High Speed Handpiece
HE18	ECO LINE High Speed Handpiece
HE20K	ECO LINE High Speed Handpiece
HE20KL	ECO LINE High Speed Handpiece with Light
HE21K	ECO LINE High Speed Handpiece
HE21KL	ECO LINE High Speed Handpiece with Light
HE21N	ECO LINE High Speed Handpiece
HE21NL	ECO LINE High Speed Handpiece with Light
HE21SL	ECO LINE High Speed Handpiece with Light
HE21W	ECO LINE High Speed Handpiece
HE21WL	ECO LINE High Speed Handpiece with Light
HE22K	ECO LINE High Speed Handpiece
HE22KL	ECO LINE High Speed Handpiece with Light
HE22N	ECO LINE High Speed Handpiece
HE22NL	ECO LINE High Speed Handpiece with Light
HE22W	ECO LINE High Speed Handpiece
HE22WL	ECO LINE High Speed Handpiece with Light
HP21KL	PRIME LINE High Speed Handpiece with Light
HP21NL	PRIME LINE High Speed Handpiece with Light
HP21SL	PRIME LINE High Speed Handpiece with Light
HP21WL	PRIME LINE High Speed Handpiece with Light
HP22KL	PRIME LINE High Speed Handpiece with Light
HP22NL	PRIME LINE High Speed Handpiece with Light
HP22WL	PRIME LINE High Speed Handpiece with Light

Artikel Item	Beschreibung Description
LB01	BASIC LINE Straight Handpiece
LB01W	BASIC LINE Straight Handpiece
LB02	BASIC LINE Straight Handpiece
LB11/11	BASIC LINE Contra Angle Handpiece
LB11/11C	BASIC LINE Contra Angle Handpiece
LB11W	BASIC LINE Contra Angle Handpiece
LB41/11	BASIC LINE Contra Angle Handpiece
LB41/11P	BASIC LINE Contra Angle Handpiece
LBH11	BASIC LINE Contra Angle Head
LBH11C	BASIC LINE Contra Angle Latch Type Head
LBH11P	BASIC LINE Contra Angle Prophy Head
LC01	CLASSIC LINE Straight Handpiece
LC01L	CLASSIC LINE Straight Handpiece with Light
LC11	CLASSIC LINE Contra Angle Body
LC11L	CLASSIC LINE Contra Angle Body with Light
LC27	CLASSIC LINE Contra Angle Body
LC27L	CLASSIC LINE Contra Angle Body with Light
LC74	CLASSIC LINE Contra Angle Body
LC74L	CLASSIC LINE Contra Angle Body with Light
LCH11	CLASSIC LINE Contra Angle Head
LCH16	CLASSIC LINE Contra Angle Head
LCH21	CLASSIC LINE Contra Angle Head
LCH21P	CLASSIC LINE Contra Angle Prophy Head
LE01	ECO LINE Straight Handpiece
LE01L	ECO LINE Straight Handpiece with Light
LE11	ECO LINE Contra Angle Handpiece
LE11L	ECO LINE Contra Angle Handpiece with Light
LE148	ECO LINE Contra Angle Handpiece
LE148L	ECO LINE Contra Angle Handpiece with Light
LE148LP	ECO LINE Contra Angle Handpiece with Light
LE148P	ECO LINE Contra Angle Handpiece
LE15	ECO LINE Contra Angle Handpiece
LE15L	ECO LINE Contra Angle Handpiece with Light
LE16	ECO LINE Contra Angle Handpiece
LE16L	ECO LINE Contra Angle Handpiece with Light
LE21	ECO LINE Contra Angle Handpiece
LE21L	ECO LINE Contra Angle Handpiece with Light
LE21P	ECO LINE Contra Angle Handpiece
LE27	ECO LINE Contra Angle Handpiece
LE27L	ECO LINE Contra Angle Handpiece with Light
LE54	ECO LINE Contra Angle Handpiece
LE54L	ECO LINE Contra Angle Handpiece with Light
LE54LP	ECO LINE Contra Angle Handpiece with Light
LE54P	ECO LINE Contra Angle Handpiece
LE74	ECO LINE Contra Angle Handpiece
LE74L	ECO LINE Contra Angle Handpiece with Light

Artikel Item	Beschreibung Description
LP01L	PRIME LINE Straight Handpiece with Light
LP11L	PRIME LINE Contra Angle Body with Light
LP15L	PRIME LINE Contra Angle Body with Light
LP27L	PRIME LINE Contra Angle Body with Light
LP74L	PRIME LINE Contra Angle Body with Light
LPH11	PRIME LINE Contra Angle Head
LPH16	PRIME LINE Contra Angle Head
LPH21	PRIME LINE Contra Angle Head