

CE₀₁₂₃ declaration of conformity

according to the medical device directive 93/42/EC

We

company **MK-dent GmbH**
Eichenweg 7B
22941 Bargteheide

hereby declare with sole responsibility that the following products

air pressure operated handpieces and turbines for driving dental rotating instruments with FG-shaft as well as straight and contra angle handpieces and accessories as listed on page 2-4

are classified as class IIa medical devices and are following the applicable "essential requirements" according to annex I of the above-named directive.

The specifications are conformed with the following harmonized standards:

DIN EN ISO 13485, DIN EN ISO 15223, DIN EN 1041, DIN EN 1641, DIN EN ISO 7405, DIN EN ISO 14457, DIN 13940-1, DIN EN ISO 14971, DIN EN ISO 17664, DIN EN ISO 9168, DIN EN ISO 9687, ISO 3964, DIN EN ISO 10993-1, DIN EN ISO 10993-5.

The conformity evaluation procedures are realized according to annex V and VII of directive 93/42/EEG under control of our notified body TÜV Süd Product Service GmbH, Ridlerstr. 65, 80339 Munich, Germany.

EC Certificate No. G2 15 09 33150 013 – valid until 2018-08-04.

This declaration of conformity is valid until 04.08.2018 for all products which are produced according the updated technical documentation from 28th of August 2015 if no change is made to the products.

MK-dent[®] GmbH
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Bargteheide, 11th of May 2016

Managing director
M. Kleene

List of item number:

Ref. No.	Description
LP01L	PRIME LINE Straight Handpiece with light
LP11L	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
LC01	CLASSIC LINE Straight Handpiece without light
LC01L	CLASSIC LINE Straight Handpiece with light
LC11	CLASSIC LINE Contra Angle Body without light
LC11L	CLASSIC LINE Contra Angle Body with light
LC27	CLASSIC LINE Contra Angle Body without light
LC27L	CLASSIC LINE Contra Angle Body with light
LC74	CLASSIC LINE Contra Angle Body without light
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
LE01	ECO LINE Straight Handpiece without light
LE01L	ECO LINE Straight Handpiece with light
LE11	ECO LINE Contra Angle Handpiece without light
LE11L	ECO LINE Contra Angle Handpiece with light
LE16	ECO LINE Contra Angle Handpiece without light
LE16L	ECO LINE Contra Angle Handpiece with light
LE21	ECO LINE Contra Angle Handpiece without light
LE21L	ECO LINE Contra Angle Handpiece with light
LE27	ECO LINE Contra Angle Handpiece without light
LE27L	ECO LINE Contra Angle Handpiece with light
LE54	ECO LINE Contra Angle Handpiece without light
LE54L	ECO LINE Contra Angle Handpiece with light
LE74	ECO LINE Contra Angle Handpiece without light
LE74L	ECO LINE Contra Angle Handpiece with light
LE148	ECO LINE Contra Angle Handpiece without light
LE148L	ECO LINE Contra Angle Handpiece with light
LB01	BASIC LINE Straight Handpiece
LB02	BASIC LINE Straight Handpiece
LB11	BASIC LINE Contra Angle Bottom Part
LB11/11	BASIC LINE Contra Angle Handpiece
LB11/11C	BASIC LINE Contra Angle Handpiece
LB41	BASIC LINE Contra Angle Bottom Part
LB41/11	BASIC LINE Contra Angle Handpiece
LB41/11P	BASIC LINE Contra Angle Handpiece
LBH11	BASIC LINE Contra Angle Head
LBH11P	BASIC LINE Contra Angle Head

Ref. No.	Description
LBH11C	BASIC LINE Contra Angle Head
HP21KL	PRIME LINE High Speed Handpiece with light
HP22KL	PRIME LINE High Speed Handpiece with light
HP21NL	PRIME LINE High Speed Handpiece with light
HP22NL	PRIME 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
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
HE18	ECO LINE High Speed Handpiece
HE21K	ECO LINE High Speed Handpiece
HE21KL	ECO LINE High Speed Handpiece with light
HE22K	ECO LINE High Speed Handpiece
HE22KL	ECO LINE High Speed Handpiece with light
HE21N	ECO LINE High Speed Handpiece
HE21NL	ECO LINE High Speed Handpiece with light
HE22N	ECO LINE High Speed Handpiece
HE22NL	ECO LINE High Speed Handpiece with light
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
QC4012K	Quick Connector
QC4014K	Quick Connector
QC5015K	Quick Connector
QC5016K	6-hole Quick Connector
QC6016K	6-hole Quick Connector
QC5016KW	6-hole Quick Connector with spray regulation system
QC6016KW	6-hole Quick Connector with spray regulation system
QC4014NT	Quick Connector
QC5016NT	Quick Connector
QC6016NT	Quick Connector
QC4014W	Quick Connector

Ref. No.	Description
QC5016W	Quick Connector
QC5016SW	6-hole Quick Connector with spray regulation system
QC6016SW	6-hole Quick Connector with spray regulation system