

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 and electric motors for dental use”

Ref. No. : AM0002, AM0004, AM0012, AM1004, AM0014, AM1006, EM1190K

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 ISO 14971, DIN
EN ISO 17664, DIN EN ISO 9168, DIN EN ISO 14457, DIN EN ISO 13294.

The conformity evaluation procedures are realized according to annex V and VII
of directive 93/42/EWG 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
Eichenweg 7B
D - 22941 Bargteheide
Tel. 04532 / 400 49-0 - Fax 04532 / 400 49-10

Bargteheide, 11th of May 2016

Managing director
M. Kleene