

CERTIFICATE



ISO 14001:2015

DEKRA Certification GmbH hereby certifies that the organization

KaVo Dental GmbH

Bismarckring 39, 88400 Biberach, Deutschland

for the scope of certification:

design, development, manufacture, service / repair and sales of dental treatment units, dental motors, dental treatment lights, dental polymerization handpieces, dental intraoral cameras / dental caries diagnosis devices, dental turbines, dental air polishing devices / dental powders, dental tartar removal devices / scalers, dental cleaning and care devices, dental laboratory devices, dental surgery devices, manufacture of dental turbines
(sites see annex)

has established and maintains an environmental management system according to the above mentioned standard. The conformity was adduced with audit report no. A22051467.

Certificate registration no.:	170423057
Validity of previous certificate:	--
Certificate valid from:	2023-04-13
Certificate valid to:	2026-04-12

Language translation


Dr. Rolf Krökel
DEKRA Certification GmbH, Stuttgart, 2023-04-13



Annex to the Certificate no. 170423057

valid from 2023-04-13 to 2026-04-12

The following sites / organizations belong to the certificate above:

Headquarters		Scope of certification
KaVo Dental GmbH	Bismarckring 39 88400 Biberach Deutschland	See page 1
at the following sites / at the organizations at the following sites		Scope of certification
1.	KaVo Dental GmbH Bahnhofstraße 20 88447 Warthausen Deutschland	manufacture, service / repair and sales of dental treatment units, dental motors, dental treatment lights, dental polymerization handpieces, dental intraoral cameras / caries diagnosis devices, dental handpieces & turbines, dental powder jet devices / dental powders, dental tartar removal devices / scalers, dental cleaning and care devices, dental laboratory equipment, dental surgery equipment


Dr. Rolf Krökel
DEKRA Certification GmbH, Stuttgart, 2023-04-13



EU Certificate

for the assessment of the
quality management system



according to Medical Device Regulation (EU) 2017/745 Annex IX Chapter I+III

As a Notified Body of the European Union DEKRA Certification GmbH certifies, that the
manufacturer

KaVo Dental GmbH

Single Registration Number (SRN): DE-MF-000006471

Bismarckring 39, 88400 Biberach, Germany

applies a quality management system according to Annex IX Chapter I+III of the Medical Device Regulation (EU) 2017/745 for the medical devices listed in the annex. This certificate is based on the assessments listed in CNo50512-00 and is only valid in conjunction with the successful completion of the annual surveillance audits.

EU Certificate no.: 51512-60-00-00

Certificate valid from:

2024-05-24

Certificate valid to:

2026-09-28

Digitally signed by Markus
RAINER Kopf
Date: 2024-05-24 14:13:05+02:00



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

BS-MDR-092

DEKRA Certification GmbH, Stuttgart 2024-05-24
Notified Body ID number: 0124

Annex to the EU Certificate no. 51512-60-00-00

Following device categories are included in this certificate:

Class IIa

MDA 0311

Basic UDI-DI

Dental Treatment Units	++EKAVG001YA
Dental Intraoral Cameras and Diagnostic Devices	++EKAVG513ZA
Dental Multifunctional Handpieces	++EKAVG101YF
Dental straight and contra-angle Handpieces Straight and contra-angle Handpieces Air motor instruments	++EKAVG502Z5 ++EKAVG507ZF
Dental Turbines	++EKAVG501Z3
Dental Scaler Air-powered	++EKAVG503Z7
Dental Powder Jet Handpieces	++EKAVG505ZB
Dental Motors Air motors Low-voltage motors	++EKAVG508ZH ++EKAVG510Z4
Dental treatment and surgical Devices Treatment Devices Surgical Devices	++EKAVG511Z6 ++EKAVG512Z8