

CERTIFICATE



EN ISO 13485:2016 + AC:2018 + A11:2021

DEKRA Certification GmbH hereby certifies that the organization

KaVo Dental GmbH

Scope of certification:

Design and Development, Manufacture, Service / Repair and Distribution of Dental Treatment Units, Dental Motors, Dental Lights, Dental Polymerization Devices, Dental Intraoral Cameras / Caries Diagnostic Devices, Dental Handpieces & Turbines, Dental Powder-Jet Handpieces / Dental Powders, Dental Scalers, Dental Care & Maintenance Systems, Dental Laboratory Devices, Devices for Dental Surgery

Certified location:

Bismarckring 39, 88400 Biberach, Germany
(further locations see annex)

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 51512-R4-00.

Certificate registration no.: 51512-21-01_EN

Validity of previous certificate: 2024-09-28

Certificate valid from: 2024-09-29

Certificate valid to: 2027-09-28



Annex to the Certificate No. 51512-21-01

valid from 2024-09-29 to 2027-09-28

The following locations/companies belong to the certificate above:

	Headquarters	Certified location	Scope of certification
	KaVo Dental GmbH	Bismarckring 39 88400 Biberach Deutschland	see page 1
	at the following locations/at the companies at the following locations		Scopes of certification
1.		Bahnhofstraße 20 88447 Warthausen Deutschland	Manufacture, Service / Repair and Distribution of Dental Treatment Units, Dental Motors, Dental Lights, Dental Polymerization Devices, Dental Intraoral Cameras / Caries Diagnostic Devices, Dental Handpieces & Turbines, Dental Powder-Jet Handpieces / Dental Powders, Dental Scalers, Dental Care & Maintenance Systems, Dental Laboratory Devices, Devices for Dental Surgery



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

E.M.S. Electro Medical Systems S.A.

Single Registration Number (SRN): CH-MF-000026136

Chemin de la Vuarpillièrè 31, 1260 Nyon, Switzerland

Name, address of the authorized representative:

E.M.S. France SARL, 32 Rte de Pontarlier, 39460 Foncine-Le-Haut, France

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 CNo50081-00 and is only valid in conjunction with the successful completion of the annual surveillance audits.

EU Certificate no.: 50081-60-00-04

Certificate valid from:

2025-05-09

Certificate valid to:

2025-12-16

Previous certificate no. 50081-60-00-03, issued on 2025-05-05



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

BS-MDR-092

DEKRA Certification GmbH, Stuttgart
Notified Body ID number: 0124

Annex to the EU Certificate no. 50081-60-00-04

Following devices/device categories are included in this certificate:

Class Is

- Stone Catcher Basic UDI-DI: 07613353039LH

Class IIa

ExtraCorporal Shock Waves therapy systems

- DolorClast SMART20 Device Family Basic UDI-DI: 07613353026L8
- DolorClast Master Device Family Basic UDI-DI: 07613353031KZ
- DolorClast Radial Device Family Basic UDI-DI: 07613353034L7
- DolorClast Focused Device Family Basic UDI-DI: 07613353057LK
- DolorClast Handpieces Basic UDI-DI: 07613353046LE

Piezo-ceramic Systems for dentistry

- PIEZON 250 Device Family Basic UDI-DI: 07613353030KX
- PIEZON Kits Device Family Basic UDI-DI: 07613353028LC
- PIEZON Handpieces Family Basic UDI-DI: 07613353021 KW
- PIEZON Instruments Family Basic UDI-DI: 07613353037LD

Air abrasion / air polisher devices for dental prophylaxis

- AIRFLOW Handy 3.0 Device Family Basic UDI-DI: 07613353033L5
- AIRFLOW Handpieces Family Basic UDI-DI: 07613353035L9
- PERIOFLOW Handpieces Family Basic UDI-DI: 07613353016L5
- PERIOFLOW Nozzles Family Basic UDI-DI: 07613353036LB

Air abrasion / air polisher devices for dental prophylaxis with Piezo-ceramic Systems for dentistry

- AIRFLOW Prophylaxis Master and AIRFLOW One Device Family Basic UDI-DI: 07613353002KS
- GBT Machine AIRFLOW Prophylaxis Master Device Family Basic UDI-DI: 07613353058LM

Dental prophylaxis powders

- AIRFLOW Powders Basic UDI-DI: 07613353020KU

Change to previous certificate: Addition of product Stone Catcher

EC Declaration of Conformity
according to Annex IV
Medical Device Regulation 2017/745/EU

KAVO

Manufacturer

KaVo Dental GmbH
Bismarckring 39
88400 Biberach
Germany
www.kavo.com

EUDAMED SRN

DE-MF-000006471

Product / REF

Dental straight and contra-angle handpieces

Basic UDI-DI

++EKAVG502Z5

Classification

Class IIa, Rule 9

Intended use of the product (s)

This medical device is:

▪ Intended for dental treatment only. All other types of use (of) or modifications to the product are not permitted and can be hazardous.

▪ The medical device is intended for the following applications:

S81 / 8:1 / S321 / L52 / L62 / L66 B / L67 / L68 / L68B:

Cavity preparation and endodontics

S19 / S31 / S33 / E31:

The medical device can be used in combination with a polishing tool to support the periodontal treatment by polishing with a rotating tool.

L31:

The INTRA prophylaxis heads can be used in combination with the rubber calyces and polishing brushes to support the periodontopathy treatment through rotary polishing.

M10 / E10:

Removal of carious material, Cavities and crown preparations, Removal of fillings, Processing of tooth and restoration surfaces.

S10:

The removal of caries, drilling, removal of fillings, surface processing as well as the polishing and smoothing of dental and restoration surfaces.

E15 / E20 / MC01GL / MC01BL / S20:

Cavity preparation, Caries excavation, Endodontics, Processing of tooth and restoration surfaces

S53 / L53:

Endodontics as well as support for periodontal treatment by means of polishing.

M07 L / M20 L / M29 L:

Removal of carious material, cavity and crown preparation, removal of fillings, processing of tooth and restoration surfaces

M25 / M05 / M45 / E25 / MC01RL:

Removal of carious material, Removal of fillings, Processing of tooth and restoration surfaces, Tooth, cavity and crown preparations

E61:

Depending on the files employed, the medical device can be used for the finishing of box preparations, for bevelling in composite fillings and inlays / onlays, for edge finishing in crowns as well as for the removal of rough, proximal filling surfaces and edges of crowns.

S80:

Drilling, caries excavation, endodontics, processing of tooth and restoration surfaces.

L80:

Cavity preparation, treatment of tooth and restoration surfaces.

L3 / L3Y:

Endodontics

L61 R / L61 G:

The INTRA EVA head L61 G/R can be used in combination with Proxoshape, Bevelshape, Cavishape, Rootshape files, Ortho-Strips as well as the Margin-Shaper made by Intensiv in the appropriate indications.

**EC Declaration of Conformity
according to Annex IV**
Medical Device Regulation 2017/745/EU



L22:

Microsurgery

▪ A medical device according to relevant national statutory regulations

For detailed description of product and accessories see instructions for use

EC Marking in accordance with

Regulation on medical devices (MDR)

2017/745/EU

Common Specifications

Currently not available

Statement

We declare under our sole responsibility that the products manufactured by us to which this declaration relates conform to the essential safety and performance requirements in accordance with the provisions of the above directives and their applicable annexes.

This declaration is supported by the certificate with registration no. 51512-60-00-00 according to the Conformity assessment procedure of Directive 2017/745/EU, Annex IX.

Notified Body

2017/745/EU

DEKRA Certification GmbH

Handwerkstrasse 15
70565 Stuttgart

0124

Validity

Issued on

2024-11-05

Valid until

2026-09-28



Senior Director Regulatory Affairs
Quality Assurance

EC Declaration of Conformity
according to Annex IV
Medical Device Regulation 2017/745/EU



Attachment I

List of considered products

Product description	Sales number	Material number	Basic UDI-DI
MASTERmatic LUX	M29 L	1.009.3580	++EKAVG502Z5
MASTERmatic LUX	M07 L	1.009.3610	++EKAVG502Z5
MASTERmatic LUX	M20 L	1.009.3620	++EKAVG502Z5
MASTERmatic LUX	M10 L	1.009.3570	++EKAVG502Z5
MASTERmatic LUX	M25 L	1.009.3630	++EKAVG502Z5
MASTERmatic LUX	M05 L	1.009.3640	++EKAVG502Z5
MASTERmatic LUX	M45 L	1.014.0280	++EKAVG502Z5
EXPERTmatic	E15 C	1.007.5531	++EKAVG502Z5
EXPERTmatic	E20 C	1.007.5541	++EKAVG502Z5
EXPERTmatic	E25 C	1.007.5551	++EKAVG502Z5
EXPERTmatic	E10 C	1.007.5560	++EKAVG502Z5
EXPERTmatic	E31 C	1.008.4998	++EKAVG502Z5
EXPERTmatic	E61 C	1.008.4999	++EKAVG502Z5
EXPERTmatic LUX	E15 L	1.007.5530	++EKAVG502Z5
EXPERTmatic LUX	E20 L	1.007.5540	++EKAVG502Z5
EXPERTmatic LUX	E25 L	1.007.5550	++EKAVG502Z5
SMARTmatic	S10	1.011.6730	++EKAVG502Z5
SMARTmatic	S10 K	1.011.6731	++EKAVG502Z5
SMARTmatic	S10 S	1.011.6732	++EKAVG502Z5
SMARTmatic	PROPHY S19	1.011.6740	++EKAVG502Z5
SMARTmatic	PROPHY S19 K	1.011.6741	++EKAVG502Z5
SMARTmatic	S20	1.011.6750	++EKAVG502Z5
SMARTmatic	S20 K	1.011.6751	++EKAVG502Z5
SMARTmatic	S20 S	1.011.6752	++EKAVG502Z5
SMARTmatic	PROPHY S31	1.011.6760	++EKAVG502Z5
SMARTmatic	PROPHY S31 K	1.011.6761	++EKAVG502Z5
SMARTmatic	S80 K	1.011.6771	++EKAVG502Z5
SMARTmatic	ENDO S81	1.011.6780	++EKAVG502Z5
<i>elements</i>			
<i>Kerr Version of S81 with same design</i>	8:1	1.011.6786	++EKAVG502Z5
SMARTmatic	ENDO S321	1.011.6790	++EKAVG502Z5
SMARTmatic	PROPHY S33	1.011.6800	++EKAVG502Z5
SMARTmatic	S53	1.011.6810	++EKAVG502Z5
INTRA Head	L80	1.004.4456	++EKAVG502Z5
INTRA Head	L62	1.008.1830	++EKAVG502Z5
INTRA Head	L66 B	1.008.1831	++EKAVG502Z5
INTRA Head	L67	1.008.1832	++EKAVG502Z5
INTRA Head	L68	1.008.1833	++EKAVG502Z5
INTRA Head	L68 B	1.008.1834	++EKAVG502Z5
INTRA Endo Head	L3	1.008.1822	++EKAVG502Z5
INTRA Endo Head	L3 Y	1.008.1823	++EKAVG502Z5

**EC Declaration of Conformity
according to Annex IV
Medical Device Regulation 2017/745/EU**



INTRA Endo Head	L53	1.008.1826	++EKAVG502Z5
INTRA EVA Head	L61 G	1.008.1828	++EKAVG502Z5
INTRA EVA Head	L61 R	1.008.1829	++EKAVG502Z5
INTRA Prophy Head	L31	1.008.1824	++EKAVG502Z5
INTRA Mini Head	L52	1.008.1825	++EKAVG502Z5
INTRA Micro Head	L22	1.008.1835	++EKAVG502Z5
EXPERTmatic	E10 C Planmeca	1.015.0740	++EKAVG502Z5
EXPERTmatic LUX	E15 L Planmeca	1.015.0730	++EKAVG502Z5
EXPERTmatic LUX	E20 L Planmeca	1.015.0670	++EKAVG502Z5
EXPERTmatic LUX	E25 L Planmeca	1.015.0660	++EKAVG502Z5
MASTERmatic LUX	M10 L Planmeca	1.015.0950	++EKAVG502Z5
MASTERmatic LUX	M07 L Planmeca	1.015.0940	++EKAVG502Z5
MASTERmatic LUX	M20 L Planmeca	1.015.0850	++EKAVG502Z5
MASTERmatic LUX	M25 L Planmeca	1.015.0910	++EKAVG502Z5
MC01GL	235500401	1.015.2700	++EKAVG502Z5
MC01BL	235500201	1.015.2710	++EKAVG502Z5
MC01RL	235500001	1.015.2720	++EKAVG502Z5

**EC Declaration of Conformity
according to Annex IV
Medical Device Regulation 2017/745/EU**

KAVO

Manufacturer	KaVo Dental GmbH Bismarckring 39 88400 Biberach Germany www.kavo.com
EUDAMED SRN	DE-MF-000006471
Product / REF	MASTERtorque LUX EXPERTtorque LUX SMARTtorque LUX SURGtorque LUX
Basic UDI-DI	++EKAVG501Z3
Classification	Class IIa, Rule 9

Intended use of the product (s)

This medical device is:

- Intended for dental treatment only. All other types of use of or modifications to the product are not permitted and can be hazardous
 - The medical device is intended for the following applications:
 - Removal of carious material
 - Removal of fillings
 - Processing of tooth and restoration surfaces
 - Cavity and crown preparations
 - A medical device according to relevant national statutory regulations
- For detailed description of product and accessories see instructions for use*

EC Marking in accordance with

Regulation on medical devices (MDR)

2017/745/EU

Common Specifications

Currently not available

Statement

We declare under our sole responsibility that the products manufactured by us to which this declaration relates conform to the essential safety and performance requirements in accordance with the provisions of the above directives and their applicable annexes.

This declaration is supported by the certificate with registration no. 51512-60-00-00 according to the Conformity assessment procedure of Directive 2017/745/EU, Annex IX.

Notified Body

2017/745/EU

DEKRA Certification GmbH

Handwerkstrasse 15
70565 Stuttgart

0124

Validity

Issued on

2024-06-03

Valid until

2026-09-28

Senior Director Regulatory Affairs
Quality Assurance

**EC Declaration of Conformity
according to Annex IV
Medical Device Regulation 2017/745/EU**



Attachment I

List of considered products

Product description	Sales number	Material number	Basic UDI-DI
MASTERtorque LUX	M9000 L	1.008.7900	++EKAVG501Z3
MASTERtorque LUX	M8900 L	1.008.7800	++EKAVG501Z3
MASTERtorque LUX	M9000 L COLOR	1.007.7100	++EKAVG501Z3
MASTERtorque LUX	M9000 L COLOR	1.007.9900	++EKAVG501Z3
MASTERtorque LUX	M9000 LS	1.008.5400	++EKAVG501Z3
MASTERtorque Mini LUX	M8700 L	3.001.0000	++EKAVG501Z3
MASTERtorque Mini LUX	M8700 LS	3.001.0600	++EKAVG501Z3
MASTERtorque Mini LUX	M8700 LY	3.001.2200	++EKAVG501Z3
EXPERTtorque LUX	E680 L	1.006.8700	++EKAVG501Z3
EXPERTtorque LUX	E679 L	1.006.9200	++EKAVG501Z3
EXPERTtorque	E680 C	1.006.9000	++EKAVG501Z3
EXPERTtorque LUX	E680 LS	1.006.4600	++EKAVG501Z3
EXPERTtorque LUX	E680 LM	1.006.4300	++EKAVG501Z3
EXPERTtorque LUX	E680 LN	1.006.4700	++EKAVG501Z3
EXPERTtorque Mini LUX	E677 L	1.007.3600	++EKAVG501Z3
EXPERTtorque LUX	E675 L	1.006.6400	++EKAVG501Z3
EXPERTtorque Mini LUX	E677 LM	1.006.3800	++EKAVG501Z3
EXPERTtorque Mini LUX	E677 LN	1.006.0100	++EKAVG501Z3
SMARTtorque LUX	S619 L	1.008.1641	++EKAVG501Z3
SMARTtorque	S619 C	1.008.1642	++EKAVG501Z3
SMARTtorque Mini LUX	S615 L	1.008.1643	++EKAVG501Z3
SMARTtorque	S609 C	1.008.1644	++EKAVG501Z3
SMARTtorque Mini	S605 C	1.008.1645	++EKAVG501Z3
SURGtorque LUX	S459 L	3.000.4808	++EKAVG501Z3
SURGtorque	S459 C	3.000.5063	++EKAVG501Z3
EXPERTtorque LUX	E679 L Planmeca	1.015.0830	++EKAVG501Z3
EXPERTtorque LUX	E680 L Planmeca	1.015.0680	++EKAVG501Z3
MASTERtorque LUX	M8900 L Planmeca	1.015.0840	++EKAVG501Z3
MASTERtorque LUX	M9000 L Planmeca	1.015.0920	++EKAVG501Z3
MT02L	55001	1.015.2730	++EKAVG501Z3

CERTIFICATE



EN ISO 13485:2016 + AC:2018 + A11:2021

DEKRA Certification GmbH hereby certifies that the organization

E.M.S. Electro Medical Systems S.A.

Scope of certification:

Design, manufacturing, distribution and servicing of medical devices and accessories for dentistry, urology and orthopedics

Certified location:

Chemin de la Vuarpillière 31, 1260 Nyon, Switzerland
(further locations see annex)

has established and maintains a quality management system according to the above mentioned standard.
The conformity was adduced with audit report no. 50081-R3-00.

Certificate registration no.: 50081-21-00

Certificate valid from: 2024-04-23

Validity of previous certificate: 2024-04-22

Certificate valid to: 2026-06-14

DEKRA Certification GmbH, Stuttgart, 2024-04-23



Annex to the Certificate No. 50081-21-00

valid from 2024-04-23 to 2026-06-14

The following locations/companies belong to the certificate above:

	Headquarters	Certified location	Scope of certification
	E.M.S. Electro Medical Systems S.A.	Chemin de la Vuarpillière 31 1260 Nyon Switzerland	see page 1
	at the following locations/at the companies at the following locations		Scopes of certification
1.		Rte. de Champ-Colin 2 1260 Nyon Switzerland	Manufacturing of medical devices and accessories for dentistry, urology and orthopedics.
2.		Rte. de Champ-Colin 18 1260 Nyon Switzerland	Manufacturing and logistic activities of medical devices and accessories for dentistry, urology and orthopedics.
3.		Rte. de Pontarlier 32 39460 Foncine-le-Haut France	Manufacturing of medical devices and accessories for dentistry, urology and orthopedics



DEKRA Certification GmbH, Stuttgart, 2024-04-23