

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



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 periodontopathy 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 / Private Label Blanco 10: Removal of carious material, cavity and crown preparations, removal of fillings, processing of tooth and restoration surfaces.

S10: Removal of carious material, Cavity preparation, Removal of fillings, Processing, polishing and smoothing of tooth and restoration surfaces.

E15 / E20 / MC01GL / MC01BL / S20 / Private Label Blanco 15 / Private Label Blanco 20: Cavity preparation, Caries excavation, Endodontics, Processing of tooth and restoration surfaces.

S53 / L53: Endodontics, Support for periodontal treatment by means of polishing.

M07 L / M20 L / M29 L: Removal of carious material, Cavity and crown preparations, removal of fillings, Processing of tooth and restoration surfaces.

M25 / M05 / M45 / E25 / MC01RL / Private Label Blanco 25 / YK25L: Removal of carious material, Removal of fillings, Processing of tooth and restoration surfaces, tooth, cavity and crown preparations.

E61: The medical device, depending on the files used, is intended for the following applications: Finishing box preparations, Chamfering for composite fillings and inlays/onlays, Edge finishing for crown preparation, Removal of proximal fillings surfaces and crown edges.

S80: Cavity preparation, Caries excavation, Endodontics, Processing of tooth and restoration surfaces.

L80: In connection with the corresponding shank, the medical device is intended for the following uses: 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. Please comply with the manufacturer's instructions.

L22: Microsurgical interventions

- A medical device according to relevant national statutory regulations.

For detailed description of product and accessories see instructions for use

EU Marking in accordance with

Regulation on medical devices (MDR)

2017/745/EU

Common Specifications

Currently not available

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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 regulation above and their applicable annexes.

This declaration is supported by the certificate with registration no. 51512-60-00-01 according to the conformity assessment procedure of regulation 2017/745/EU, Annex IX.

Notified Body
2017/745/EU

DEKRA Certification GmbH
Handwerkstraße 15
70565 Stuttgart

0124

Validity

Issued on
Valid until

2026-01-22
2026-09-28

A handwritten signature in black ink, appearing to read 'K. Reisenauer'.

Klaus Reisenauer
Senior Director Regulatory Affairs
Quality Assurance

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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>	8:1	1.011.6786	++EKAVG502Z5
<i>Kerr Version of S81 with same design</i>			
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

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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 Propy Head	L31	1.008.1824	++EKAVG502Z5
INTRA Mini Head	L52	1.008.1825	++EKAVG502Z5
INTRA Micro Head	L22	1.008.1835	++EKAVG502Z5

Planmeca

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

FARO

MC01GL	235500401	1.015.2700	++EKAVG502Z5
MC01BL	235500201	1.015.2710	++EKAVG502Z5
MC01RL	235500001	1.015.2720	++EKAVG502Z5

YOSHIDA

MaxiDrive	YK25L	1.015.5628	++EKAVG502Z5
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