EC 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 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.

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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 **DEKRA Certification GmbH** **0124**
2017/745/EU Handwerkstrasse 15
70565 Stuttgart

Validity
Issued on 2024-06-26
Valid until 2026-09-28

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
elements *Kerr Version of S81 with same design*	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	L80	1.004.4456	++EKAVG502Z5
INTRA	L3	1.008.1822	++EKAVG502Z5
INTRA	L3 Y	1.008.1823	++EKAVG502Z5
INTRA	L31	1.008.1824	++EKAVG502Z5
INTRA	L52	1.008.1825	++EKAVG502Z5
INTRA	L53	1.008.1826	++EKAVG502Z5
INTRA	L61 G	1.008.1828	++EKAVG502Z5
INTRA	L61 R	1.008.1829	++EKAVG502Z5

INTRA	L62	1.008.1830	++EKAVG502Z5
INTRA	L66 B	1.008.1831	++EKAVG502Z5
INTRA	L67	1.008.1832	++EKAVG502Z5
INTRA	L68	1.008.1833	++EKAVG502Z5
INTRA	L68 B	1.008.1834	++EKAVG502Z5
INTRA	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