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

Primus 1058 Life / 1.010.5000
ESTETICA E30 / 1.005.0000
ESTETICA E70 Vision / 1.010.7050
ESTETICA E80 Vision / 1.010.7000
KaVo uniQa / 2.021.0000
KaVo amiQa / 2.024.0000

Basic UDI-DI ++EKAVG001YA

Classification Class IIa, Rule 9

Intended use of the product (s)
- Positioning of the patient
- Supply of instruments and accessories to perform the treatment
- Separation of treatment particles (amalgam, tooth substance, organic materials,…), that are sucked during the treatment or absorbed via the cuspidor and finally separated for proper disposal
- The treatment unit must only be used and operated by adequately trained and medically trained personnel.
- The treatment unit must only be mounted and maintained by adequately trained specialists.

EU 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 regulation and their applicable annexes.

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

Notified Body **DEKRA Certification GmbH** **0124**
2017/745/EU
Handwerkstraße 15
70565 Stuttgart

Validity
Issued on 2026-09-29
Valid until 2031-09-28

Klaus Reisenauer
Sr. Director Regulatory Affairs and Quality Assurance, Corporate Compliance & EHS

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Attachment I

List of considered products

Product description	Material number	Basic UDI-DI
Primus 1058 Life	1.010.5000	++EKAVG001YA
ESTETICA E30	1.005.0000	++EKAVG001YA
ESTETICA E70 Vision	1.010.7050	++EKAVG001YA
ESTETICA E80 Vision	1.010.7000	++EKAVG001YA
KaVo uniQa	2.021.0000	++EKAVG001YA
KaVo amiQa	2.024.0000	++EKAVG001YA

Attachment II

Compatible medical devices / accessories within the system (Article 22, MDR 2017/745/EU)

Medical device / Accessory	Material number	BASIS UDI	Classification	Legal manufacturer	E70 / E80 Vision	1058 Life	E30	KaVo uniQa	KaVo amiQa
KaVo Lumina	2.021.5000 2.021.5050	++EKAVG200YJ	Class I (Rule 13)	KaVo Dental GmbH	x	x	x	x	x
KaVolux 540 LED U	1.008.2700 0.799.8080	++EKAVG200YJ	Class I (Rule 13)	KaVo Dental GmbH	x	-	-	x	x
KaVolux 540 LED T	1.008.2700 0.799.8080	++EKAVG200YJ	Class I (Rule 13)	KaVo Dental GmbH	-	x	x	-	-
FARO MAIA	1.004.2500 1.009.3450	803402839MAIA9H	Class I (Rule 10)	FARO	-	x	x	-	x
DEKASEPTOL Gel	1.006.0010	n.a. MDD	Class IIa (Rule 15)	Prisman	x	x	x	x	x
DEKAPURE Gel *(nur USA/CAN)*	1.012.8361	n.a. MDD	Class IIa (Rule 15)	Prisman	x	x	x	-	-
OXYGENAL 6	0.489.3451	542502099KAVOA3	Class I (Rule 1)	Roam Technology	x	x	x	x	x

Satelec MiniLED	1.003.8119	03609820027821 03609820027876 03609820027975	Class IIa (Rule 9)	Satelec	**x**	**x**	**x**	**x**	**x**
Mehrfunktionshandstück, abgewinkelt	0.773.0000	++EKAVG101YF	Class IIa (Rule 12)	KaVo Dental GmbH	**x**	**x**	**-**	**x**	**x**
Mehrfunktionshandstück, gerade	0.773.0010	++EKAVG101YF	Class IIa (Rule 12)	KaVo Dental GmbH	**x**	**x**	**-**	**x**	**x**
3-Funktionshandstück, abgewinkelt	0.773.0500	++EKAVG101YF	Class IIa (Rule 12)	KaVo Dental GmbH	**x**	**x**	**x**	**x**	**x**
3-Funktionshandstück, gerade	0.773.0510	++EKAVG101YF	Class IIa (Rule 12)	KaVo Dental GmbH	**x**	**x**	**x**	**x**	**x**
Dreifunktionshandstück One	1.009.2724 1.009.7840	++EKAVG101YF	Class IIa (Rule 12)	KaVo Dental GmbH	**-**	**-**	**x**	**-**	**-**
KaVo ProXam iCam	1.011.2130 1.011.2129	88000969IOC01LG	Class I (Rule 13)	Dentall	**x**	**x**	**-**	**x**	**x**
DIAGNOcam Vision Full HD	1.013.1500	++EKAVG513ZA	Class IIa (Rule 10)	KaVo Dental GmbH	**x**	**x**	**-**	**x**	**x**
CONEXIO	1.010.2000	++EKAVG312YW	Class I (Rule 11)	KaVo Dental GmbH	**x**	**x**	**x**	**x**	**x**
KaVo CONNECTbase	1.014.7618	++EKAVG312YW	Class I (Rule 11)	KaVo Dental GmbH	**x**	**-**	**-**	**x**	**x**
MULTIflex LED Kupplung 465	1.007.3197 0.553.1550 0.553.1600	++EKAVG501Z3	Class IIa (Rule 9)	KaVo Dental GmbH	**x**	**x**	**x**	**x**	**x**
KaVo eSCALER	1.014.0600	++EKAVG518ZL	Class IIa (Rule 9)	KaVo Dental GmbH	**x**	**x**	**x**	**x**	**x**
PiezoLED	1.007.3995	07613353021KW	Class IIa (Rule 9)	EMS	**x**	**x**	**x**	**x**	**x**
PIEZOsoft	1.009.8488	07613353021KW	Class IIa (Rule 9)	EMS	**-**	**x**	**x**	**-**	**-**
INTRA LUX MOTOR 701	1.001.8776	++EKAVG510Z4	Class IIa (Rule 9)	KaVo Dental GmbH	**-**	**x**	**x**	**x**	**x**
INTRA LUX KL 703 LED	1.007.0150	++EKAVG510Z4	Class IIa (Rule 9)	KaVo Dental GmbH	**x**	**x**	**x**	**x**	**x**
INTRA K-LUX Motor K200	1.000.6717	++EKAVG510Z4	Class IIa (Rule 9)	KaVo Dental GmbH	**x**	**-**	**-**	**x**	**x**
Chirurgie-Motor INTRA S600 LED	1.008.8000	++EKAVG510Z4	Class IIa (Rule 9)	KaVo Dental GmbH	**x**	**-**	**-**	**x**	**x**
INTRA L-LUX 181 L	0.535.5210	++EKAVG508ZH	Class IIa (Rule 9)	KaVo Dental GmbH	**-**	**x**	**x**	**-**	**-**
KaVo Minilight 3F / KaVo Minilight G3F	1.015.3933 1.015.3934 1.015.3935 1.015.3936 1.015.3937 1.015.3938 1.015.3939 1.015.3940	MDD 93/42 EC	Class IIa (Rule 11)	Luzzani	**x**	**x**	**x**	**x**	**x**