

EU 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

Surgical straight and contra-angle handpieces

Basic UDI-DI

++EKAVG502Z5

Classification

Class IIa, Rule 9

Intended use of the product (s)

S201 / S11 / CL09-3 / 3610:

This medical device is:

- Intended for dental treatment only. All other types of use or modifications to the product are not permitted and can be hazardous.
- The medical device is intended for the following applications: surgical application areas, e.g.:
Placing an implant, bone augmentation, sinus lift, dental extraction, implantology and oral-maxillo-facial surgery.
- A medical device according to relevant national statutory regulations.

S15:

This medical device is:

- Intended only for dental treatment by a dental professional, the product must not be modified or used for any other purpose since this may be hazardous
- The medical device is designed for general dentistry and oral surgery. Application fields include, e.g.:
Hemisection, dental extraction, root removal, osteotomy, removal of wisdom teeth, apicectomy, removal of carious material, tooth, cavity and crown preparations and processing of fillings.
- 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

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

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Validity
Issued on
Valid until

2025-03-31
2026-09-28

A handwritten signature in blue 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
INTRA	3610 N1	0.524.5600	++EKAVG502Z5
INTRA	3610 N2	0.524.5610	++EKAVG502Z5
INTRA	3610 N3	0.524.5620	++EKAVG502Z5
INTRA	CL 10	1.002.0911	++EKAVG502Z5
INTRA	CL 3-09	1.002.3693	++EKAVG502Z5
<i>INTRA</i>	<i>CL 3</i>	<i>1.001.8993</i>	++EKAVG502Z5
<i>INTRA</i>	<i>CL 09</i>	<i>1.001.9258</i>	++EKAVG502Z5
SURGmatic	S11 L	1.009.1010	++EKAVG502Z5
SURGmatic	S201 XL Pro	1.013.7541	++EKAVG502Z5
SURGmatic	S201 L Pro	1.013.7540	++EKAVG502Z5
SURGmatic Head	S201 XL Pro	1.013.8662	++EKAVG502Z5
SURGmatic Head	S201 L Pro	1.013.8648	++EKAVG502Z5
SURGmatic	S15 L Pro	1.014.4000	++EKAVG502Z5
SURGmatic <i>(Brazil INS)</i>	S15 L Pro	1.015.3690	++EKAVG502Z5
SURGmatic <i>(Brazil INS)</i>	S201 XL Pro	1.015.3691	++EKAVG502Z5
SURGmatic <i>(Brazil INS)</i>	S201 L Pro	1.015.3693	++EKAVG502Z5
SURGmatic <i>(Brazil INS)</i>	S11 L	1.015.3695	++EKAVG502Z5
