

**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**

Powder jet handpieces

**Basic UDI-DI**

++EKAVG505ZB

**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 or modifications to the product are not permitted and can be hazardous. The medical device is intended for the following applications: Removal of discoloration and bacterial plaque, orthodontics, cleaning prior to fissure sealing, prosthetics, conservative and aesthetic dentistry. Please refer also to the Instructions for Use.

- 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

2024-05-24

Valid until

2026-09-28

  
Klaus Reisenauer  
Senior Director Regulatory Affairs  
Quality Assurance

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**Attachment I**

List of considered products

<b>Product description</b>	<b>Sales number</b>	<b>Material number</b>	<b>Basic UDI-DI</b>
PROPHYflex 4 Wave	not used	3.002.8000	++EKAVG505ZB
PROPHYflex 4 Lime	not used	3.002.8200	++EKAVG505ZB
PROPHYflex 4 Flamingo	not used	3.002.8800	++EKAVG505ZB
PROPHYflex 4 S Wave	not used	3.004.5900	++EKAVG505ZB
PROPHYflex 4 S Lime	not used	3.004.5930	++EKAVG505ZB
PROPHYflex 4 S Flamingo	not used	3.004.5950	++EKAVG505ZB
PROPHYflex perio tip	not used	2.000.0922	++EKAVG505ZB
Refill PROPHYflex perio tip	not used	1.010.0287	++EKAVG505ZB
PROPHYflex 4 Perio Kit	not used	1.011.9403	++EKAVG505ZB
PROPHYflex Perio Kit	not used	1.009.3731	++EKAVG505ZB

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