EC Declaration of Conformity according to Annex IV

Medical Device Regulation 2017/745/EU



Manufacturer

KaVo Dental GmbH Bismarckring 39 88400 Biberach Germany

EUDAMED SRN

DE-MF-000006471

www.kavo.com

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 of 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**

0124

Handwerkstrasse 15 70565 Stuttgart

Validity

Issued on Valid until

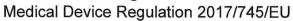
2024-05-24 2026-09-28

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 |
|-----------------------------|--------------|-----------------|--------------|
| 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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