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 MULTIflex connectors

H+EKAVG501Z3

Classification Class IIa, Rule 9

Intended use of the product (s)

The 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 coupling the standard supply hose (DIN EN ISO 9168) to MULTIflex-compatible dental handpieces, turbine handpieces, air motors, scalers, prophylaxis handpieces etc.
- 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
 2024-06-03

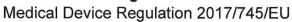
 Valid until
 2026-09-28

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
MULTIflex Coupling	465 LED	1.007.3197	++EKAVG501Z3
MULTIflex LUX Coupling	465 LRN	0.553.1550	++EKAVG501Z3
MULTIflex Coupling	465 RN	0.553.1600	++EKAVG501Z3
MULTIflex Coupling	460 LED	1.007.3201	++EKAVG501Z3
MULTIflex Coupling	460 LE	1.001.7599	++EKAVG501Z3
MULTIflex Coupling	Midwest	0.553.1390	++EKAVG501Z3
MULTIflex Coupling	457	0.553.1210	++EKAVG501Z3
SonicFill Multiflex Coupling	35134	1.008.0581	++EKAVG501Z3
MULTIflex Coupling	460 E	1.001.7600	++EKAVG501Z3
QC02LED	55501	1.015.2740	++EKAVG501Z3

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