

**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

Primus 1058 Life / 1.010.5000
ESTETICA E30 / 1.005.0000
ESTETICA E50 Life / 1.011.1100
ESTETICA E70 Vision / 1.010.7050
ESTETICA E80 Vision / 1.010.7000
KaVo uniQa / 2.021.0000

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.

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

Attachment I

List of considered products

Product description	Material number	Basic UDI-DI
Primus 1058 Life	1.010.5000	++EKAVG001YA
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ESTETICA E50 Life	1.011.1100	++EKAVG001YA
ESTETICA E70 Vision	1.010.7050	++EKAVG001YA
ESTETICA E80 Vision	1.010.7000	++EKAVG001YA
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