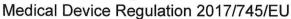
EC Declaration of Conformity according to Annex IV





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

H+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 DEKRA Certification GmbH 0124

2017/745/EU Handwerkstrasse 15 70565 Stuttgart

 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

Product description	Material number	Basic UDI-DI	
Primus 1058 Life	1.010.5000	++EKAVG001YA	
ESTETICA E30	1.005.0000	++EKAVG001YA	
ESTETICA E50 Life	1.011.1100	++EKAVG001YA	
ESTETICA E70 Vision	1.010.7050	++EKAVG001YA	
ESTETICA E80 Vision	1.010.7000	++EKAVG001YA	
KaVo uniQa	2.021.0000	++EKAVG001YA	

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