

**EU 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

DIAGNOcam Vision Full HD / 1.011.1213
DIAGNOcam Vision Full HD (Unit version) / 1.013.1500
DIAGNOcam Vision Full HD (A-dec) / 1.015.3700

Basic UDI-DI

++EKAVG513ZA

Classification

Class IIa, Rule 10

Intended use of the product (s)

The application range of the DIAGNOcam Vision Full HD ranges from images in the oral cavity of the patient to images taken outside the mouth (i.e. facial images). The images support diagnosis by detection of smooth surface caries, occlusal caries, proximal caries, initial caries, secondary caries, and tooth fractures. The DIAGNOcam Vision Full HD is designed for use by a trained professional in the field of dentistry.

For detailed description of product and accessories see instructions for use

EU 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 regulation above and their applicable annexes.

This declaration is supported by the certificate with registration no. 51512-60-00-01 according to the conformity assessment procedure of regulation 2017/745/EU, Annex IX.

Notified Body

2017/745/EU

DEKRA Certification GmbH

Handwerkstraße 15
70565 Stuttgart

0124


Validity

Issued on

2025-03-31

Valid until

2026-09-28


Klaus Reisenauer
Senior Director Regulatory Affairs
Quality Assurance

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Attachment I

Compatible accessories (Article 2, MDR 2017/745/EU)

Product	Material number	BASIS UDI	Classification	Legal manufacturer
DIAGNOcam Software	1.009.5110	-	Accessory	KaVo Denal GmbH
TWAIN Interface	1.014.8400	-	Accessory	KaVo Denal GmbH
