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
DIAGNOcam Vision Full HD / 1.011.1213
DIAGNOcam Vision Full HD (Unit version) / 1.013.1500

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

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

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KAVO

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