

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

RONDOflex plus 360 / 1.002.2179

Basic UDI-DI

++EKAVG505ZB

Classification

Class IIa, Rule 9

Intended use of the product (s)

This 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 RONDOflex plus is an air abrasion system that accelerates aluminium oxide particles in an air jet to a high speed to abrade material from the surface of teeth.

▪ A medical device according to relevant national statutory regulations

RONDOflex plus is designed for the following indications:

- Preparation for fissure sealing
- Opening and expanding fissures
- Creating micromechanical retention for adhesive restorations to the enamel and dentin with a subsequent acid etching technique
- Preparation of small carious lesions
- Preparation of the adhesive surfaces of brackets
- Cleaning and removal of residual adhesive from bridges, crowns, etc. (extraoral)

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

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Validity

Issued on

Valid until

2025-03-31

2026-09-28



Klaus Reisenauer
Senior Director Regulatory Affairs
Quality Assurance
