

**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**

RONDOflex plus 360 / 1.002.2179

**Basic UDI-DI**

++EKA VG505ZB

**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*

**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**


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**Validity**

Issued on  
Valid until

2024-05-24  
2026-09-28



Klaus Reisenauer  
Senior Director Regulatory Affairs  
Quality Assurance

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