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

SONICflex
SONICflex LUX
SONICflex quick

Basic UDI-DI

++EKAVG503Z7

Classification

Class IIa, Rule 9

Intended use of the product (s)
This medical device is
- Intended for dental treatment only. All other types of use of or modifications to the product are not permitted and can be hazardous.
- A medical device according to relevant national statutory regulations.

The SONICflex dental handpiece can be used in combination with the SONICflex tips for calculus removal, prophylaxis, endodontics, periodontics, surgery, in conservative 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
Valid until

2024-05-24
2026-09-28

Klaus Reisenauer
Senior Director Regulatory Affairs
Quality Assurance

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KAVO

Attachment I

List of considered products

Product description	Sales number	Material number	Basic UDI-DI
SONICflex	2000 N	0.571.5020	++EKAVG503Z7
SONICflex	2003	1.000.4246	++EKAVG503Z7
SONICflex	2003 L	1.000.4243	++EKAVG503Z7
SONICflex LUX	2004 LM	1.006.0965	++EKAVG503Z7
SONICflex quick	2008	1.005.9311	++EKAVG503Z7
SONICflex quick	2008 L	1.005.9310	++EKAVG503Z7
SONICflex quick	2008 LS	1.007.0540	++EKAVG503Z7