

Manufacturer

KaVo Dental GmbH
Bismarckring 39
88400 Biberach
Germany
www.kavo.com

EUDAMED SRN

DE-MF-000006471

Product / REF

SONICflex scaler tips

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 or modifications of the product are not permitted and can be hazardous.

SONICflex scaler:

The SONICflex scaler tips are used in combination with the SONICflex for prophylaxis, removal of sub- and supragingival calculus, and in conservative dentistry.

SONICflex cariex:

The SONICflex cariex tips are used in combination with the SONICflex for the excavation of caries.

SONICflex seal:

The SONICflex seal tip is designed for use in combination with the SONICflex for exposing and expanding fissures before sealing.

SONICflex micro and bevel:

The SONICflex micro and bevel tips are used in combination with the SONICflex for preparing and chamfering minute lesions relating to defects while preserving neighbouring teeth.

SONICflex paro:

SONICflex paro tips are used in combination with the SONICflex to remove periodontal plaque.

SONICflex endo:

The SONICflex endo set is used in combination with the SONICflex for orthograde preparation of the pulp cavity and of the upper third of the root canal.

SONICflex rootplaner:

The SONICflex rootplaner tips are used in conjunction with the SONICflex for root canal preparation.

SONICflex retro:

The SONICflex retro tips are used in conjunction with the SONICflex for retrograde root canal preparation.

SONICflex endo clean:

The SONICflex endo clean needles can be used in connection with the SONICflex for sonic-activated cleaning of the prepared root canal.

SONICflex clean:

The SONICflex clean brush set can be used in combination with the SONICflex instrument for professional tooth cleaning, removal of stains and discolouration, as well as for dental polishing. An additional use of the system, is preoperative cleaning of fissures, cavities and crown preparations.

SONICflex prep ceram and prep CAD/CAM:

The SONICflex prep ceram and prep CAD/CAM tips are used in combination with the SONICflex for finishing preparation of proximal cavity edges for laboratory and chairside fabricated ceramic inlays.

SONICflex prep gold:

The SONICflex prep gold tips are used in combination with the SONICflex for finishing preparation of proximal cavity edges for laboratory fabricated gold inlays.

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SONICflex cem:

The SONICflex cem tip is used in combination with the SONICflex to vibrate inlays/ onlays.

SONICflex implant:

The SONICflex implant set is used in conjunction with the SONICflex for subgingival and supragingival removal of soft stains on dental implants and abutments.

SONICflex prep crown:

The SONICflex prep crown tips are used in combination with the SONICflex for the finishing work on crown edges in crown preparation.

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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Attachment I

List of considered products

Product description	Sales number	Material number	Basic UDI-DI
Calculus removal			
SONICflex scaler tip set	not used	1.000.4983	++EKAVG503Z7
SONICflex scaler tip set A	not used	1.005.9328	++EKAVG503Z7
SONICflex scaler tip no. 5	not used	0.571.5171	++EKAVG503Z7
SONICflex scaler tip no. 6	not used	0.571.5181	++EKAVG503Z7
SONICflex scaler tip no. 7	not used	0.571.5191	++EKAVG503Z7
SONICflex scaler tip no. 8	not used	0.571.5371	++EKAVG503Z7
SONICflex scaler tip no. 5 A	not used	1.005.8949	++EKAVG503Z7
SONICflex scaler tip no. 6 A	not used	1.005.8950	++EKAVG503Z7
SONICflex scaler tip no. 7 A	not used	1.005.8951	++EKAVG503Z7
SONICflex scaler tip no. 8 A	not used	1.006.1953	++EKAVG503Z7
Minimally invasive caries therapy			
SONICflex cari-ex 0.8 tip no. 42	not used	1.000.7105	++EKAVG503Z7
SONICflex cari-ex 1.2 tip no. 43	not used	1.000.7167	++EKAVG503Z7
SONICflex cari-ex 1.0 tip no. 71	not used	1.000.7362	++EKAVG503Z7
SONICflex cari-ex 1.4 tip no. 72	not used	1.000.7363	++EKAVG503Z7
SONICflex cari-ex 0.8 tip no. 42 A	not used	1.006.1980	++EKAVG503Z7
SONICflex cari-ex 1.2 tip no. 43 A	not used	1.006.1981	++EKAVG503Z7
SONICflex cari-ex 1.0 tip no. 71 A	not used	1.006.2002	++EKAVG503Z7
SONICflex cari-ex 1.4 tip no. 72 A	not used	1.006.2004	++EKAVG503Z7
SONICflex seal tip no. 45			
SONICflex seal tip no. 45 A	not used	1.007.1506	++EKAVG503Z7
SONICflex micro tip no. 30			
SONICflex micro tip no. 31	not used	0.571.6811	++EKAVG503Z7
SONICflex micro tip no. 33	not used	0.571.6801	++EKAVG503Z7
SONICflex micro tip no. 32	not used	0.571.6821	++EKAVG503Z7
SONICflex micro tip no. 32	not used	0.571.6831	++EKAVG503Z7
SONICflex micro tip no. 30 A	not used	1.006.1969	++EKAVG503Z7
SONICflex micro tip no. 31 A	not used	1.006.1971	++EKAVG503Z7
SONICflex micro tip no. 32 A	not used	1.006.1973	++EKAVG503Z7
SONICflex micro tip no. 33 A	not used	1.006.1975	++EKAVG503Z7
SONICflex bevel tip no. 58			
SONICflex bevel tip no. 59	not used	0.571.7392	++EKAVG503Z7
SONICflex bevel tip no. 59	not used	0.571.7382	++EKAVG503Z7
SONICflex bevel tip no. 58 A	not used	1.006.1988	++EKAVG503Z7
SONICflex bevel tip no. 59 A	not used	1.006.1990	++EKAVG503Z7
Prophylaxis			
SONICflex paro tip set	not used	0.571.0371	++EKAVG503Z7
SONICflex paro tip set A	not used	1.006.2020	++EKAVG503Z7
SONICflex paro tip no. 60	not used	0.571.7402	++EKAVG503Z7
SONICflex paro tip no. 61	not used	0.571.7412	++EKAVG503Z7

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SONICflex paro tip no. 62	not used	0.571.7422	++EKAVG503Z7
SONICflex paro tip no. 60 A	not used	1.006.1934	++EKAVG503Z7
SONICflex paro tip no. 61 A	not used	1.006.1935	++EKAVG503Z7
SONICflex paro tip no. 62 A	not used	1.006.1936	++EKAVG503Z7
Prepare root canal			
SONICflex endo tip no. 66	not used	1.000.5825	++EKAVG503Z7
SONICflex endo tip no. 67	not used	1.000.5822	++EKAVG503Z7
SONICflex endo tip no. 68	not used	1.000.5823	++EKAVG503Z7
SONICflex endo tip no. 69	not used	1.000.5827	++EKAVG503Z7
SONICflex endo tip no. 70	not used	1.000.5821	++EKAVG503Z7
SONICflex endo tip no. 66 A	not used	1.006.1992	++EKAVG503Z7
SONICflex endo tip no. 67 A	not used	1.006.1994	++EKAVG503Z7
SONICflex endo tip no. 68 A	not used	1.006.1996	++EKAVG503Z7
SONICflex endo tip no. 69 A	not used	1.006.1998	++EKAVG503Z7
SONICflex endo tip no. 70 A	not used	1.006.2000	++EKAVG503Z7
SONICflex rootplaner tip no. 24			
SONICflex rootplaner tip no. 25	not used	0.571.5621	++EKAVG503Z7
SONICflex rootplaner tip no. 26	not used	0.571.5631	++EKAVG503Z7
SONICflex rootplaner tip no. 27	not used	0.571.5641	++EKAVG503Z7
SONICflex rootplaner tip no. 27	not used	0.571.5651	++EKAVG503Z7
SONICflex rootplaner tip no. 24 A	not used	1.006.1957	++EKAVG503Z7
SONICflex rootplaner tip no. 25 A	not used	1.006.1959	++EKAVG503Z7
SONICflex rootplaner tip no. 26 A	not used	1.006.1961	++EKAVG503Z7
SONICflex rootplaner tip no. 27 A	not used	1.006.1963	++EKAVG503Z7
Retrograde root canal treatment			
SONICflex retro tip no. 16	not used	0.571.5541	++EKAVG503Z7
SONICflex retro tip no. 17	not used	0.571.5581	++EKAVG503Z7
SONICflex retro tip no. 20	not used	0.571.5521	++EKAVG503Z7
SONICflex retro tip no. 21	not used	0.571.5561	++EKAVG503Z7
SONICflex retro tip no. 55	not used	0.571.7342	++EKAVG503Z7
SONICflex retro tip no. 56	not used	0.571.7322	++EKAVG503Z7
SONICflex retro tip no. 57	not used	0.571.7332	++EKAVG503Z7
SONICflex retro tip no. 16 A	not used	1.006.2036	++EKAVG503Z7
SONICflex retro tip no. 17 A	not used	1.006.2035	++EKAVG503Z7
SONICflex retro tip no. 20 A	not used	1.006.2037	++EKAVG503Z7
SONICflex retro tip no. 21 A	not used	1.006.2038	++EKAVG503Z7
SONICflex retro tip no. 55 A	not used	1.006.2039	++EKAVG503Z7
SONICflex retro tip no. 56 A	not used	1.006.2040	++EKAVG503Z7
SONICflex retro tip no. 57 A	not used	1.006.2041	++EKAVG503Z7
SONICflex endo clean 015 / XF			
SONICflex endo clean 020 / FF	not used	1.006.2042	++EKAVG503Z7
SONICflex endo clean 025 / MF	not used	1.006.2043	++EKAVG503Z7
SONICflex endo clean holder no. 96	not used	1.006.2044	++EKAVG503Z7
SONICflex endo clean holder no. 96	not used	1.008.5163	++EKAVG503Z7
SONICflex endo clean holder no. 96 A	not used	1.008.5164	++EKAVG503Z7

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Tooth cleaning

SONICflex clean tip no. 48	not used	0.571.0401	++EKAVG503Z7
SONICflex clean tip no. 48 A	not used	1.006.1982	++EKAVG503Z7
SONICflex clean brush no. 1	not used	0.571.0402	++EKAVG503Z7
SONICflex clean brush no. 2	not used	0.571.0412	++EKAVG503Z7
SONICflex clean brush no. 3	not used	0.571.0422	++EKAVG503Z7
SONICflex clean brush no. 4	not used	0.571.0432	++EKAVG503Z7
SONICflex clean brush no. 5	not used	0.571.0472	++EKAVG503Z7
SONICflex clean brush no. 6	not used	0.571.0482	++EKAVG503Z7

Preparation

SONICflex prep ceram tip no. 51	not used	0.571.7262	++EKAVG503Z7
SONICflex prep ceram tip no. 52	not used	0.571.7272	++EKAVG503Z7
SONICflex prep ceram tip no. 51 A	not used	1.006.1985	++EKAVG503Z7
SONICflex prep ceram tip no. 52 A	not used	1.006.1986	++EKAVG503Z7

SONICflex prep gold tip no. 49	not used	0.571.7212	++EKAVG503Z7
SONICflex prep gold tip no. 50	not used	0.571.7222	++EKAVG503Z7
SONICflex prep gold tip no. 49 A	not used	1.006.1983	++EKAVG503Z7
SONICflex prep gold tip no. 50 A	not used	1.006.1984	++EKAVG503Z7

SONICflex cem tip no. 12	not used	0.571.5431	++EKAVG503Z7
SONICflex cem tip no. 12 A	not used	1.006.2021	++EKAVG503Z7
SONICflex cem tip	not used	0.571.7142	++EKAVG503Z7

SONICflex prep CAD/CAM tip no. 34	not used	1.002.1984	++EKAVG503Z7
SONICflex prep CAD/CAM tip no. 35	not used	1.002.1986	++EKAVG503Z7
SONICflex prep CAD/CAM tip no. 34 A	not used	1.006.1977	++EKAVG503Z7
SONICflex prep CAD/CAM tip no. 35 A	not used	1.006.1979	++EKAVG503Z7

Implant cleaning

SONICflex implant set	not used	1.003.8167	++EKAVG503Z7
SONICflex implant set A	not used	1.006.2027	++EKAVG503Z7
SONICflex implant refill	not used	1.003.8168	++EKAVG503Z7

Crown preparation

SONICflex prep crown round tip no. 97	not used	1.008.6383	++EKAVG503Z7
SONICflex prep crown plain tip no. 98	not used	1.008.6385	++EKAVG503Z7
SONICflex prep crown round tip no. 97 A	not used	1.008.6384	++EKAVG503Z7
SONICflex prep crown plain tip no. 98 A	not used	1.008.6386	++EKAVG503Z7