

EC Declaration of Conformity



Document No.: SDS_EU_DOC_MDR_10002_16

Manufacturer:	SIRONA Dental Systems GmbH
Address:	Fabrikstraße 31 64625 Bensheim Germany
SRN:	DE-MF-000000029
Medical Device Name:	TiBase
Basic UDI-DI:	++E276Abutment01AJ
Classification according to Annex VIII (2017/745/EU):	Class II b Rule 8
Common Specifications:	-

Intended Use:
Titanium base for the manufacture of a two-piece abutment consisting of TiBase and inCoris ZI me-so or a screw-retained crown consisting of TiBase and CEREC Zirconia meso.

We declare under our sole responsibility the compliance of the medical device concerned with the requirements of the Council Regulation 2017/745/EU.

Any modification to the product, not authorized by us, will invalidate this declaration.

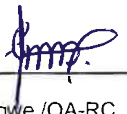
Valid from manufacturing date: 2024-09-11

The conformity of the full quality assurance system (Regulation 2017/745/EU, Annex IX) is certified by:
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Certificate ID: G10 031247 0089 Rev. 02

The identification number of the notified body for implementation of the procedure is 0123.

Bensheim, 2024-09-23

Place and date

 [Signature] Niels Plate General Manager & GVP Equipment R&D & Launch Management	 [Signature] Mr. Nyebuchi Wigwe /QA-RC Regulatory Compliance Manager
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The declaration certifies the compliance according to Annex I of Regulation 2017/745/EU.
Conditions of guarantee and liability are dealt within our General Conditions of Sale.

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Table 1: Product Variants of TiBase

No.	Product	REF No.	Content	Content
1	TiBase NB RS 3.5 L	6282474	1x Titanbasis NB RS 3.5 L	1x Abutmentschraube NB RS 1.8
2	TiBase NB RS 4.3 L	6282482	1x Titanbasis NB RS 4.3 L	1x Abutmentschraube NB RS 2.0
3	TiBase NB RS 5.0 L	6282490	1x Titanbasis NB RS 5.0 L	1x Abutmentschraube NB RS 2.0
4	TiBase NB RS 6.0 L	6282508	1x Titanbasis NB RS 6.0 L	1x Abutmentschraube NB RS 2.0
5	TiBase NB B 3.4 L	6282516	1x Titanbasis NB B 3.4 L	1x Abutmentschraube NB B 1.6
6	TiBase NB B 4.1 L	6282524	1x Titanbasis NB B 4.1 L	1x Abutmentschraube NB B 2.0
7	TiBase B 0 3.4 L	6282557	1x Titanbasis B 0 3.4 L	1x Abutmentschraube B 0 2.0
8	TiBase B 0 4.1 L	6282565	1x Titanbasis B 0 4.1 L	1x Abutmentschraube B 0 2.0
9	TiBase B 0 5.0 L	6282573	1x Titanbasis B 0 5.0 L	1x Abutmentschraube B 0 2.0
10	TiBase Z TSV 3.5 L	6282581	1x Titanbasis Z TSV 3.5 L	1x Abutmentschraube Z TSV 1.8
11	TiBase Z TSV 4.5 L	6282599	1x Titanbasis Z TSV 4.5 L	1x Abutmentschraube Z TSV 1.8
12	TiBase Z TSV 5.7 L	6282607	1x Titanbasis Z TSV 5.7 L	1x Abutmentschraube Z TSV 1.8
13	TiBase S SO 4.8 L	6284249	1x Titanbasis S SO 4.8 L	1x Abutmentschraube S SO 2.0
14	TiBase S SO 6.5 L	6284256	1x Titanbasis S SO 6.5 L	1x Abutmentschraube S SO 2.0
15	TiBase B C 3.4 S	6308048	1x Titanbasis B C 3.4 S	1x Abutmentschraube B C 1.6
16	TiBase B C 4.1 L	6308097	1x Titanbasis B C 4.1 L	1x Abutmentschraube B C 1.6
17	TiBase B C 5.0 L	6308121	1x Titanbasis B C 5.0 L	1x Abutmentschraube B C 1.6
18	TiBase S BL 3.3 L	6308154	1x Titanbasis S BL 3.3 L	1x Abutmentschraube S BL 1.6
19	TiBase S BL 4.1 L	6308337	1x Titanbasis S BL 4.1 L	1x Abutmentschraube S BL 1.6
20	TiBase NB A 4.5 L	6308188	1x Titanbasis NB A 4.5 L	1x Abutmentschraube NB A 1.6
21	TiBase NB A 5.0 L	6308253	1x Titanbasis NB A 5.0 L	1x Abutmentschraube NB A 2.0
22	TiBase 0 TS 3.5 L	6527035	1x Titanbasis 0 TS 3.5 L	1x Abutmentschraube 0 TS 1.6
23	TiBase 0 TS 4.0 L	6527043	1x Titanbasis 0 TS 4.0 L	1x Abutmentschraube 0 TS 2.0
24	TiBase BH 3.0 S	6532779	1x Titanbasis BH 3.0 S	1x Abutmentschraube BH PXMUAS UNF1-72
25	TiBase BH 3.5 L	6532894	1x Titanbasis BH 3.5 L	1x Abutmentschraube BH PXAS UNF1-72
26	TiBase BH 4.5 L	6532951	1x Titanbasis BH 4.5 L	1x Abutmentschraube BH PXAS UNF1-72
27	TiBase BH 5.7 L	6536242	1x Titanbasis BH 5.7 L	1x Abutmentschraube BH PXAS UNF1-72

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No.	Product	REF No.	Content	Content
28	TiBase AT EV 3.0 GH1 S	6586304	1x Titanbasis AT EV 3.0 GH1 S	1x Abutmentschraube AT EV 3.0
29	TiBase AT EV 3.6 GH1 S	6586312	1x Titanbasis AT EV 3.6 GH1 S	1x Abutmentschraube AT EV 3.6
30	TiBase AT EV 4.2 GH1 L	6586320	1x Titanbasis AT EV 4.2 GH1 L	1x Abutmentschraube AT EV 4.2
31	TiBase AT EV 4.8 GH1 L	6586338	1x Titanbasis AT EV 4.8 GH1 L	1x Abutmentschraube AT EV 4.8
32	TiBase AT EV 5.4 GH1 L	6586346	1x Titanbasis AT EV 5.4 GH1 L	1x Abutmentschraube AT EV 5.4
33	TiBase ANK C/ GH1 S	6586528	ZSB Titanbasis ANK C/ GH1 S	
34	TiBase ANK C/ GH2 S	6586536	ZSB Titanbasis ANK C/ GH2 S	
35	TiBase ANK /X GH1 S	6586544	ZSB Titanbasis ANK /X GH1 S	
36	TiBase ANK /X GH2 S	6586551	ZSB Titanbasis ANK /X GH2 S	
37	TiBase TM 3.5 S	6531854	1x Titanbasis TM 3.5 S	1x Abutmentschraube TM 1.4
38	TiBase TM 4.0 S	6532829	1x Titanbasis TM 4.0 S	1x Abutmentschraube TM 1.6
39	TiBase TM 4.5 S	6532837	1x Titanbasis TM 4.5 S	1x Abutmentschraube TM 1.6
40	TiBase TM 5.0 S	6544360	1x Titanbasis TM 5.0 S	1x Abutmentschraube TM 1.6
41	TiBase TM 6.0 S	6544378	1x Titanbasis TM 6.0 S	1x Abutmentschraube TM 1.6
42	TiBase XiVE 3.0 S	6597319	1x Titanbasis XiVE 3.0 S	1x Abutmentschraube XiVE 1.6
43	TiBase XiVE 3.4 S	6597327	1x Titanbasis XiVE 3.4 S	1x Abutmentschraube XiVE 1.6
44	TiBase XiVE 3.8 S	6597335	1x Titanbasis XiVE 3.8 S	1x Abutmentschraube XiVE 1.6
45	TiBase XiVE 4.5 L	6597343	1x Titanbasis XiVE 4.5 L	1x Abutmentschraube XiVe 1.6
46	TiBase XiVE 5.5 L	6597350	1x Titanbasis XiVE 5.5 L	1x Abutmentschraube XiVE 1.6
47	TiBase AT TX 3.0 S	6598085	1x Titanbasis AT TX 3.0 S	1x Abutmentschraube AT TX 1.4
48	TiBase AT TX 3.5/4.0 L	6598093	1x Titanbasis AT TX 3.5/4.0 L	1x Abutmentschraube AT TX 1.6
49	TiBase AT TX 4.5/5.0 L	6598101	1x Titanbasis AT TX 4.5/5.0 L	1x Abutmentschraube AT TX 2.0

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Table 2: Product Variants of Abutments Screws

No.	Produktname	REF	Inhalt
1	Abutment Screw B C 3.4, 4.1, 5.0	6460450	2x Abutmentschraube B C 1.6
2	Abutment Screw B O 3.4, 4.1, 5.0	6460468	2x Abutmentschraube B O 2.0
3	Abutment Screw NB A 4.5	6460484	2x Abutmentschraube NB A 1.6
4	Abutment Screw NB A 5.0	6460492	2x Abutmentschraube NB A 2.0
5	Abutment Screw NB B 3.4	6460500	2x Abutmentschraube NB B 1.6
6	Abutment Screw NB B 4.1	6460518	2x Abutmentschraube NB B 2.0
7	Abutment Screw NB RS 3.5	6460526	2x Abutmentschraube NB RS 1.8
8	Abutment Screw NB RS 4.3, 5.0, 6.0	6460534	2x Abutmentschraube NB RS 2.0
9	Abutment Screw S BL 3.3, 4.1	6460542	2x Abutmentschraube S BL 1.6
10	Abutment Screw S SO 4.8, 6.5	6460567	2x Abutmentschraube S SO 2.0
11	Abutment Screw Z TSV 3.5, 4.5, 5.7	6460575	2x Abutmentschraube Z TSV 1.8
12	Abutment Screw O TS 3.5	6561208	2x Abutmentschraube O TS 1.6
13	Abutment Screw O TS 4.0	6561232	2x Abutmentschraube O TS 2.0
14	Abutment Screw BH 3.0	6561240	2x Abutmentschraube BH PXMUAS UNF1-72
15	Abutment Screw BH 3.5, 4.5, 5.7	6561257	2x Abutmentschraube BH PXAS UNF1-72
16	Abutment Screw AT EV 3.0	6586262	2x Abutmentschraube AT EV 3.0
17	Abutment Screw AT EV 3.6	6586270	2x Abutmentschraube AT EV 3.6
18	Abutment Screw AT EV 4.2	6586288	2x Abutmentschraube AT EV 4.2
19	Abutment Screw AT EV 4.8	6586296	2x Abutmentschraube AT EV 4.8
20	Abutment Screw AT EV 5.4	6593714	2x Abutmentschraube AT EV 5.4
21	Abutment Screw TM 3.5	6561265	2x Abutmentschraube TM 1.4
22	Abutment Screw TM 4.0, 4.5, 5.0, 6.0	6561273	2x Abutmentschraube TM 1.6
23	Abutment Screw XiVE 3.0	6597434	2x Abutmentschraube XiVE 1.4
24	Abutment Screw XiVE 3.4, 3.8, 4.5, 5.5	6597442	2x Abutmentschraube XiVE 1.6
25	Abutment Screw AT TX 3.0	6598051	2x Abutmentschraube AT TX 1.4
26	Abutment Screw AT TX 3.5/4.0	6598069	2x Abutmentschraube AT TX 1.6
27	Abutment Screw AT TX 4.5/5.0	6598077	2x Abutmentschraube AT TX 2.0