

DECLARATION OF CONFORMITY

We, DR. IHDE DENTAL AG
Dorfplatz 11
CH-8737 Gommiswald
Switzerland

declare under our sole responsibility that the medical devices

Two-Part Dental Implants:

HC2, HC 6+2, HC2 PLUS MU (Hexacone), TPG, SSO/STO/STW, BLP (Bone Level Plus), Xi (Xign)

OneWay Biomed: GIH2, GIH PLUS MU, GIO/STO/STW, GBL, GXi

see list attachment DOC TPI

meets all the provisions of **the directive 93/42/EEC** which apply to it.

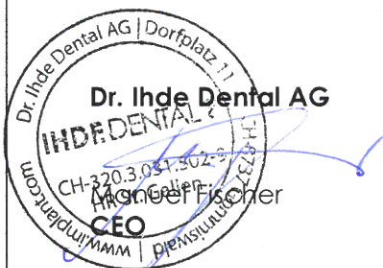
Conformity assessment procedure:
 Annex II (without section 4) MDD 93/42 EEC(2007/47/EC)
 Certificate Nr: (HD60130544)

Classification: Class IIb Medical Devices

Notified Body:
 TUV Rheinland: CE1936

This declaration loses the validity on 29.11.2022

Gommiswald, 17.02.2020



Annex DOC TPI

Article Nr	Description
412202	HC2 3.7 8 Implant, wide thread part, Ti6Al4V
412203	HC2 3.7 10 Implant, wide thread part, Ti6Al4V
412204	HC2 3.7 13 Implant, wide thread part, Ti6Al4V
412205	HC2 3.7 15 Implant, wide thread part, Ti6Al4V
412206	HC2 4.5 8 Implant, wide thread part, Ti6Al4V
412207	HC2 4.5 10 Implant, wide thread part, Ti6Al4V
412208	HC2 4.5 11.5 Implant, wide thread part, Ti6Al4V
412209	HC2 4.5 13 Implant, wide thread part, Ti6Al4V
412210	HC2 3.7 11.5 Implant, wide thread part, Ti6Al4V
412211	HC2 5.5 8 Implant, wide thread part, Ti6Al4V
412212	HC2 5.5 10 Implant, wide thread part, Ti6Al4V
412213	HC2 5.5 11.5 Implant, wide thread part, Ti6Al4V
412214	HC2 5.5 13 Implant, wide thread part, Ti6Al4V
412217	HC2 4.5 6+2 Implant, wide thread part, Ti6Al4V
412218	HC2 5.5 6+2 Implant, wide thread part, Ti6Al4V
412220	HC2 3.3 8 Implant, wide thread part, Ti6Al4V
412221	HC2 3.3 10 Implant, wide thread part, Ti6Al4V
412222	HC2 3.3 11.5 Implant, wide thread part, Ti6Al4V
412223	HC2 3.3 13 Implant, wide thread part, Ti6Al4V
412224	HC2 3.3 15 Implant, wide thread part, Ti6Al4V
412225	HC PLUS MU 15, Gr. 3.3 13, Implant, Ti6Al4V
412226	HC PLUS MU 15, Gr. 3.3 15, Implant, Ti6Al4V
412227	HC PLUS MU 15, Gr. 3.3 17, Implant, Ti6Al4V
412228	HC PLUS MU 15, Gr. 3.3 19, Implant, Ti6Al4V
412229	HC PLUS MU 15, Gr. 3.3 21, Implant, Ti6Al4V
412230	HC PLUS MU 15, Gr. 3.3 23, Implant, Ti6Al4V
412235	HC PLUS MU 15, Gr.4.1 10, Implant, Ti6Al4V
412236	HC PLUS MU 15, Gr.4.1 13, Implant, Ti6Al4V
412237	HC PLUS MU 15, Gr.4.1 15, Implant, Ti6Al4V
412238	HC PLUS MU 15, Gr.4.1 17, Implant, Ti6Al4V
412239	HC PLUS MU 15, Gr.4.1 19, Implant, Ti6Al4V
412240	HC PLUS MU 15, Gr.4.1 21, Implant, Ti6Al4V
412241	HC PLUS MU 15, Gr.4.1 23, Implant, Ti6Al4V
412250	HC PLUS MU 0, Gr. 3.3 13, Implant, Ti6Al4V
412251	HC PLUS MU 0, Gr. 3.3 15, Implant, Ti6Al4V
412252	HC PLUS MU 0, Gr. 3.3 17, Implant, Ti6Al4V
412253	HC PLUS MU 0, Gr. 3.3 19, Implant, Ti6Al4V
412254	HC PLUS MU 0, Gr. 3.3 21, Implant, Ti6Al4V
412255	HC PLUS MU 0, Gr. 3.3 23, Implant, Ti6Al4V
412259	HC PLUS MU 0, Gr. 4.1 10, Implant, Ti6Al4V
412260	HC PLUS MU 0, Gr. 4.1 13, Implant, Ti6Al4V
412261	HC PLUS MU 0, Gr. 4.1 15, Implant, Ti6Al4V
412262	HC PLUS MU 0, Gr. 4.1 17, Implant, Ti6Al4V
412263	HC PLUS MU 0, Gr. 4.1 19, Implant, Ti6Al4V
412264	HC PLUS MU 0, Gr. 4.1 21, Implant, Ti6Al4V
412265	HC PLUS MU 0, Gr. 4.1 23, Implant, Ti6Al4V

Article Nr	Description
413200	HC 2.9 13 Implant, incl. CSTI, Ti6Al4V
413201	HC 2.9 15 Implant, incl. CSTI, Ti6Al4V
413202	HC 3.7 8 Implant, incl. CSTI, Ti6Al4V
413203	HC 3.7 10 Implant, incl. CSTI, Ti6Al4V
413204	HC 3.7 13 Implant, incl. CSTI, Ti6Al4V
413205	HC 3.7 15 Implant, incl. CSTI, Ti6Al4V
413206	HC 4.5 8 Implant, incl. CSTI, Ti6Al4V
413207	HC 4.5 10 Implant, incl. CSTI, Ti6Al4V
413208	HC 4.5 11.5 Implant, incl. CSTI, Ti6Al4V
413209	HC 4.5 13 Implant, incl. CSTI, Ti6Al4V
413210	HC 3.7 11.5 Implant, incl. CSTI, Ti6Al4V
413211	HC 5.5 8 Implant incl. CSTI, Ti6Al4V
413212	HC 5.5 10 Implant incl. CSTI, Ti6Al4V
413213	HC 5.5 11.5 Implant incl. CSTI, Ti6Al4V
413214	HC 5.5 13 Implant incl. CSTI, Ti6Al4V
413220	HC 3.3 8 Implant incl. CSTI, Ti6Al4V
413221	HC 3.3 10 Implant incl. CSTI, Ti6Al4V
413222	HC 3.3 11.5 Implant incl. CSTI, Ti6Al4V
413223	HC 3.3 13 Implant incl. CSTI, Ti6Al4V
413224	HC 3.3 15 Implant incl. CSTI, Ti6Al4V
413300	HC 4.1 8 Implant, incl. CSTI, Ti6Al4V
413301	HC 4.1 10 Implant, incl. CSTI, Ti6Al4V
413302	HC 4.1 11.5 Implant, incl. CSTI, Ti6Al4V
413303	HC 4.1 13 Implant, incl. CSTI, Ti6Al4V
420000	Allfit SSO 3.3 9 Implant, Ti6Al4V
420001	Allfit SSO 3.3 11 Implant, Ti6Al4V
420002	Allfit SSO 3.3 13 Implant, Ti6Al4V
420003	Allfit SSO 3.3 15 Implant, Ti6Al4V
420004	Allfit SSO 4.1 7 Implant, TiGr4
420005	Allfit SSO 4.1 9 Implant, TiGr4
420006	Allfit SSO 4.1 11 Implant, TiGr4
420007	Allfit SSO 4.1 13 Implant, TiGr4
420008	Allfit SSO 4.1 15 Implant, TiGr4
420009	Allfit SSO 4.1 17 Implant, TiGr4
420010	Allfit SSO 4.8 7 Implant, TiGr4
420011	Allfit SSO 4.8 9 Implant, TiGr4
420012	Allfit SSO 4.8 11 Implant, TiGr4
420013	Allfit SSO 4.8 13 Implant, TiGr4
420015	Allfit STW 4.8 7 Implant, Ti6Al4V
420016	Allfit STW 4.8 9 Implant, Ti6Al4V
420017	Allfit STW 4.8 11 Implant, Ti6Al4V
420018	Allfit STW 4.8 13 Implant, Ti6Al4V
420019	Allfit STW 4.8 15 Implant, Ti6Al4V
420020	Allfit STO 3.7 9 Implant, Ti6Al4V
420021	Allfit STO 3.7 11 Implant, Ti6Al4V
420022	Allfit STO 3.7 13 Implant, Ti6Al4V
420023	Allfit STO 3.7 15 Implant, Ti6Al4V
420024	Allfit STO 4.1 7 Implant, Ti6Al4V
420025	Allfit STO 4.1 9 Implant, Ti6Al4V

Article Nr	Description
420026	Allfit STO 4.1 11 Implant, Ti6Al4V
420027	Allfit STO 4.1 13 Implant, Ti6Al4V
420028	Allfit STO 4.1 15 Implant, Ti6Al4V
420029	Allfit STO 4.8 7 Implant, Ti6Al4V
420030	Allfit STO 4.8 9 Implant, Ti6Al4V
420031	Allfit STO 4.8 11 Implant, Ti6Al4V
420032	Allfit STO 4.8 13 Implant, Ti6Al4V
420033	Allfit STO 4.8 15 Implant, Ti6Al4V
422000	Xi 3.0 11.5 Implant Ti6Al4V
422001	Xi 3.0 13 Implant Ti6Al4V
422002	Xi 3.0 15 Implant Ti6Al4V
422003	Xi 3.4 8 Implant Ti6Al4V
422004	Xi 3.4 10 Implant Ti6Al4V
422005	Xi 3.4 11.5 Implant Ti6Al4V
422006	Xi 3.4 13 Implant Ti6Al4V
422007	Xi 3.4 15 Implant Ti6Al4V
422008	Xi 3.8 8 Implant Ti6Al4V
422009	Xi 3.8 10 Implant Ti6Al4V
422010	Xi 3.8 11.5 Implant Ti6Al4V
422011	Xi 3.8 13 Implant Ti6Al4V
422012	Xi 3.8 15 Implant Ti6Al4V
422013	Xi 4.5 6+2 Implant Ti6Al4V
422014	Xi 4.5 8 Implant Ti6Al4V
422015	Xi 4.5 10 Implant Ti6Al4V
422016	Xi 4.5 11.5 Implant Ti6Al4V
422017	Xi 4.5 13 Implant Ti6Al4V
422018	Xi 4.5 15 Implant Ti6Al4V
422019	Xi 5.5 6+2 Implant Ti6Al4V
900500	BLP 3.3 8 NC Implant Ti6Al4V
900501	BLP 3.3 10 NC Implant Ti6Al4V
900502	BLP 3.3 12 NC Implant Ti6Al4V
900503	BLP 3.3 14 NC Implant Ti6Al4V
900504	BLP 4.1 8 RC Implant Ti6Al4V
900505	BLP 4.1 10 RC Implant Ti6Al4V
900506	BLP 4.1 12 RC Implant Ti6Al4V
900507	BLP 4.1 14 RC Implant Ti6Al4V
900508	BLP 4.8 8 RC Implant Ti6Al4V
900509	BLP 4.8 10 RC Implant Ti6Al4V
900510	BLP 4.8 12 RC Implant Ti6Al4V
900511	BLP 4.8 14 RC Implant Ti6Al4V
420106	TPG 4.1 8 impant Ti6Al4V
420107	TPG 4.1 10 impant Ti6Al4V
420104	TPG 4.1 12 impant Ti6Al4V
420100	TPG 4.1 15 impant Ti6Al4V
420101	TPG 4.1 17 impant Ti6Al4V
420102	TPG 4.1 19 impant Ti6Al4V
420103	TPG 4.1 21 impant Ti6Al4V
420105	TPG 4.1 23 impant Ti6Al4V