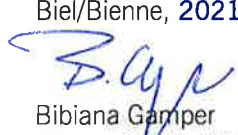






Wir, die Firma	Nous, la maison Cendres+ Métaux SA Rue de Boujean 122 CH-2501 Biel/Bienne	We, the company
Bevollmächtigter	Mandataire Cendres+ Métaux France SAS Les petites Buffeteries F-49124 St-Barthélémy d'Anjou	Authorized Representative
erklären hiermit in alleiniger Verantwortung, dass die folgenden Produkte	déclarons sous notre seule responsabilité que les produits suivants	declare under our sole responsibility that the following products
gemäss beiliegender Liste	CM Class I selon liste annexée List of CM Class I Version 2	according to attached list
konform sind zu den folgenden normativen Dokumenten:	sont conformes aux documents normatifs suivants:	are in conformity with the following normative documents:
Grundlegende Anforderungen gemäss Anhang I, 93/42/EWG, 2007/47/EG	Exigences essentielles selon l'annexe I, 93/42/CEE, 2007/47/CE	Essential Requirements according to annex I, 93/42/EEC, 2007/47/EC
Normen: vgl. beiliegende Liste	Normes: cf. liste annexée	Standards: see attached list
	List of laws, standards and norms Product Group Class I according MDD Edition 07	
Klassifizierung gemäss Anhang IX, 93/42/EWG: vgl. beiliegende Liste	Classification selon l'annexe IX, 93/42/CEE: Cf. liste annexée des produits List of CM Class I Version 2	Classification according to annex IX, 93/42/EEC: see attached list of products
Konformitätsbewertungsverfahren: 93/42/EWG Klasse I: Anhang VII Übrige Klassen: Anhang II (ohne Abschnitt 4)	Procédure d'évaluation de la conformité: 93/42/CEE Classe I: Annexe VII Autres classes: Annexe II (sans section 4)	Conformity assessment procedure: 93/42/EEC Class I: Annex VII All other classes: Annex II (Without section 4)
Benannte Stelle: Klasse I: Benannte Stelle nicht erforderlich. Übrige Klassen: MDC (CE 0483)	Organisme notifié: Classe I: Pas d'organisme notifié nécessaire. Autres classes: MDC (CE 0483)	Notified Body: Class I: No notified body needed. All other classes: MDC (CE 0483)
Gültigkeit	Validité 2024-04-30	Validity
Änderungen: Änderungsantrag MD5-2943, MD5-3008	Modifications: demande modification MD5-2943, MD5-3008	Changes: change request MD5-2943, MD5-3008
Diese Konformitätserklärung wird mit den folgenden Unterschriften beglaubigt: Biel/Bienne, 2021-01-25 	Cette déclaration de conformité est certifiée par les signatures suivantes: 	This declaration is certified by the following signatures:
Bibiana Gamper Director of Quality & Regulatory	Remi Meier Product Safety Officer	

#	Catalog Number	Product Name	Device group	Family	Class MDD	Rule MDD
1	07000211	CM LOC® Activator for Elitor® Retention insert	CM LOC®	Anchors		1
2	07000204	CM LOC® Analog	CM LOC®	Anchors		1
3	07000202	CM LOC® Block-out Spacer	CM LOC®	Anchors		5, 1st indent
4	CM031-03487-01	CM LOC® Block-out Spacer	CM LOC®	Anchors		5, 1st indent
5	07000217	CM LOC® Housing Extractor	CM LOC®	Anchors		1
6	07000213	CM LOC® Impression part	CM LOC®	Anchors		5, 1st indent
7	07000200	CM LOC® Instrument Set	CM LOC®	Anchors		6, 2nd indent
8	07000205	CM LOC® Multi-Tool for Pekkton® Retention insert	CM LOC®	Anchors		1
9	07000219	CM LOC® Parallelometer insert	CM LOC®	Anchors		1
10	05001328	CM LOC® Processing insert	CM LOC®	Anchors		5, 1st indent
11	CM031-03486-01	CM LOC® Processing insert	CM LOC®	Anchors		5, 1st indent
12	07000206	CM LOC® Screw Driver	CM LOC®	Anchors		6, 2nd indent
13	07000201	CM LOC® Spacer	CM LOC®	Anchors		5, 1st indent
14	07000223	CM LOC®FLEX Aligner	CM LOC® Flex	Anchors		
15	07000222	CM LOC®FLEX Screw Driver	CM LOC® Flex	Anchors		6, 2nd indent
16	07000312	Dalbo® Abutment Analog	Dalbo® Abutment	Anchors		1
17	070440	Dalbo®-B Spacer G	Dalbo®-B	Anchors		5, 2nd indent
18	070131	Dalbo®-Z / Dalbo®-B / Profix / Pro-Snap Parallelometer insert	Dalbo®-B	Anchors		1
19	070197	Dalbo®-Classic /-B /-Z / Profix Activator	Dalbo®-Classic	Anchors		1
20	070199	Dalbo®-Classic /-B /-Z / Profix Deactivator	Dalbo®-Classic	Anchors		1
21	072625	Dalbo®-Classic Spacer G	Dalbo®-Classic	Anchors		5, 1st indent
22	07000266	Dalbo® Abutment Screw Driver	Dalbo®-PLUS	Anchors		6, 2nd indent
23	072637	Dalbo®-PLUS / Dalbo® Classic Special parallelometer insert	Dalbo®-PLUS	Anchors		1
24	05001239	Dalbo®-PLUS Duplicating Aid	Dalbo®-PLUS	Anchors		5, 1st indent
25	072626	Dalbo®-PLUS Duplicating aid / spacer G	Dalbo®-PLUS	Anchors		5, 1st indent
26	07000024	Dalbo®-PLUS Female part gauge	Dalbo®-PLUS	Anchors		6, 2nd indent
27	07000026	Dalbo®-PLUS Gauge set	Dalbo®-PLUS	Anchors		5, 1st indent
28	072639	Dalbo®-PLUS Heating rod	Dalbo®-PLUS	Anchors		1
29	07000027	Dalbo®-PLUS Male part gauge	Dalbo®-PLUS	Anchors		6, 2nd indent
30	072609	Dalbo®-PLUS Screwdriver / Activator	Dalbo®-PLUS	Anchors		1
31	05001241	Dalbo®-PLUS Screwdriver / Activator	Dalbo®-PLUS	Anchors		1
32	07000389	Dalbo®-PLUS Screwdriver / Activator (Altatec)	Dalbo®-PLUS	Anchors		1
33	050394	Spacer disc tin	Dalbo®-PLUS	Anchors		5, 1st indent
34	070157	Dalbo®-PLUS /-Classic /-B /-Z / Profix Transfer jig	Dalbo®-Z	Anchors		1
35	070439	Dalbo®-Z Spacer G	Dalbo®-Z	Anchors		5, 1st indent
36	050392	Eccentric Spacer disc gingival	Eccentric	Anchors		5, 1st indent
37	050393	Eccentric Spacer disc occlusal	Eccentric	Anchors		5, 1st indent
38	070161	Eccentric Transfer jig	Eccentric	Anchors		1
39	070167	Eccentric Transfer jig (male part with resilience)	Eccentric	Anchors		1

40	072466	Mini-Gerber / Mini-Gerber Plus Spacer / duplicating aid G	Mini-Gerber Plus	Anchors		5, 1st indent
41	072461	Mini-Gerber PLUS / Mini-Gerber Transfer jig	Mini-Gerber Plus	Anchors		1
42	072605	Mini-Gerber PLUS Heating rod	Mini-Gerber Plus	Anchors		1
43	072460	Mini-Gerber PLUS Parallelometer insert	Mini-Gerber Plus	Anchors		1
44	072597	Mini-Gerber PLUS Special socket key	Mini-Gerber Plus	Anchors		1
45	07050004	Pro-Snap Protection cap	Pro-Snap	Anchors		1
46	07050008	Pro-Snap Seating tool	Pro-Snap	Anchors		1
47	07050006	Pro-Snap Stabilizing ring G	Pro-Snap	Anchors		1
48	07050005	Pro-Snap Transfer jig	Pro-Snap	Anchors		1
49	052080	Dolder® System Spacer micro	Ackermann-Bar	Bars		5, 1st indent
50	070198	Dolder® System / Round bar Activator set	Dolder® System	Bars		1
51	070201	Dolder® System Desactivator macro	Dolder® System	Bars		1
52	070200	Dolder® System Desactivator micro	Dolder® System	Bars		1
53	070144	Dolder® System Parallelometer insert macro (Bar attachment)	Dolder® System	Bars		1
54	072517	Dolder® System Parallelometer insert macro (Resilient bar)	Dolder® System	Bars		1
55	070143	Dolder® System Parallelometer insert micro (Bar attachment)	Dolder® System	Bars		1
56	072515	Dolder® System Parallelometer insert micro (Resilient bar)	Dolder® System	Bars		1
57	052081	Dolder® System Spacer macro	Dolder® System	Bars		5, 1st indent
58	070173	Dolder® System Transfer jig macro L50	Dolder® System	Bars		1
59	070171	Dolder® System Transfer jig micro L50	Dolder® System	Bars		1
60	052085	Round bar with rider Spacer (Tin) 200 x 0.60mm	Round Bar with Rider	Bars		5, 1st indent
61	052082	Round bar with rider Spacer (Tin) 50 x 0.60mm	Round Bar with Rider	Bars		5, 1st indent
62	072293	Round bar with rider Transfer jig	Round Bar with Rider	Bars		1
63	05003501	Plastic Sleeve for CoCr Base	CoCr Base	Prosthetics		1
64	070246	CM root canal posts Reamer (Blue) Post size 4	CM Root Canal Posts	Root canal posts		6, 2nd indent
65	070247	CM root canal posts Reamer (Green) Post size 5	CM Root Canal Posts	Root canal posts		6, 2nd indent
66	070245	CM root canal posts Reamer (Red) Post size 3	CM Root Canal Posts	Root canal posts		6, 2nd indent
67	070243	CM root canal posts Reamer (White) Post size 1	CM Root Canal Posts	Root canal posts		6, 2nd indent
68	070244	CM root canal posts Reamer (Yellow) Post size 2	CM Root Canal Posts	Root canal posts		6, 2nd indent
69	072414	CM Root canal posts and anchors Coupling piece	Dalbo®-Rotex	Root canal posts		6, 2nd indent
70	070205	Dalbo® / Baer Cylindrical Anchor Instrument For mounting of elastomeric ring	Dalbo®-Rotex	Root canal posts		1
71	070511	Dalbo®-Rotex by Dr. Dalla Bona Transfer jig	Dalbo®-Rotex	Root canal posts		1
72	070498	Dalbo®-Rotex by Dr. Dalla Bona Spanner key for spherical head	Dalbo®-Rotex	Root canal posts		6, 2nd indent
73	070500	Dalbo®-Rotex by Prof. Brunner Spanner key for spherical head	Dalbo®-Rotex	Root canal posts		6, 2nd indent
74	070512	Dalbo®-Rotex by Prof. Brunner Transfer jig	Dalbo®-Rotex	Root canal posts		1
75	072319	Root canal posts Mooser Reamer (Blue) Post size 4	Mooser Root Canal Posts	Root canal posts		6, 2nd indent
76	070288	Root canal posts Mooser Reamer (Red) Post size 3	Mooser Root Canal Posts	Root canal posts		6, 2nd indent
77	070287	Root canal posts Mooser Reamer (White) Post size 1	Mooser Root Canal Posts	Root canal posts		6, 2nd indent
78	072318	Root canal posts Mooser Reamer (Yellow) Post size 2	Mooser Root Canal Posts	Root canal posts		6, 2nd indent
79	MD.200004443	MP-Post / Pirec MP Plastic handgrip	MP Post	Root canal posts		6, 2nd indent
80	MD.200004435	Pirec spanner key	Pirec	Root canal posts		6, 2nd indent
81	070303	Rotex Spanner key (Red) Anchor size 3	Rotex®	Root canal posts		6, 2nd indent

82	070301	Rotex Spanner key (White) Anchor size 1	Rotex®	Root canal posts		6, 2nd indent
83	070302	Rotex Spanner key (Yellow) Anchor size 2	Rotex®	Root canal posts		6, 2nd indent
84	072459	Rotex-RD Spanner key Anchor size 1-3	Rotex®-RD	Root canal posts		6, 2nd indent
85	070210	CM-hex screw system Cap screw Screw tap M1.2	CM-hex screw system	Screw and retention element		1
86	070211	CM-hex screw system Cap screw Screw tap M1.4	CM-hex screw system	Screw and retention element		1
87	07000008	CM-hex screw system Hex key (for cap and pin screw)	CM-hex screw system	Screw and retention element		6, 2nd indent
88	072439	CM-hex screw system Mounting screw X (M1.2)	CM-hex screw system	Screw and retention element		1
89	072440	CM-hex screw system Mounting screw X (M1.4)	CM-hex screw system	Screw and retention element		1
90	070470	CM-hex screw system Pin screw Screw tap MF1.6x0.2	CM-hex screw system	Screw and retention element		1
91	070395	CM-hex screw system Pin screw Spiral drill Ø 1.40mm	CM-hex screw system	Screw and retention element		1
92	070213	CM-hex screw system Screw tap holder	CM-hex screw system	Screw and retention element		6, 2nd indent
93	070214	CM-hex screw system Screw tap holder (for parallelometer)	CM-hex screw system	Screw and retention element		1
94	072432	CM-hex screw system Spiral drill Ø 1.85mm	CM-hex screw system	Screw and retention element		1
95	072433	CM-hex screw system Spiral drill Ø 2.05mm	CM-hex screw system	Screw and retention element		1
96	07050012	Mini-Presso-Matic Screw for modelling	Mini-Presso-Matic	Screw and retention element		1
97	07050013	Mini-Presso-Matic Screwdriver	Mini-Presso-Matic	Screw and retention element		6, 2nd indent
98	07050014	Mini-Presso-Matic Thread tap M2.3x0.25	Mini-Presso-Matic	Screw and retention element		1
99	070146	Mini-Dalbo® / Dalbo®-S Parallelometer insert	Dalbo®-S	Slide Attachments		1
100	070176	Mini-Dalbo® Transfer jig	Mini-Dalbo®	Slide Attachments		1
101	072483	Mini-SG® F/R / Mini-SG® Insert remover	Mini-SG®	Slide Attachments		1
102	072616	Mini-SG® F/R / Mini-SG® PLUS / Mini-SG® Transfer jig	Mini-SG®	Slide Attachments		1
103	072600	Mini-SG® F/R Duplicating aid G	Mini-SG® F/R	Slide Attachments		1
104	072649	Mini-SG® PLUS Duplicating aid G	Mini-SG® Plus	Slide Attachments		1
105	072653	M-SG® Star 2 / Mini-SG® PLUS Screwdriver/Activator	Mini-SG® Plus	Slide Attachments		1
106	07000056	Mini-SG® / Mini-SG® F/R / M-SG® Star 1 Insert remover	M-SG® Star 1	Slide Attachments		1
107	07000042	Mini-SG® / M-SG® Star Transfer jig	M-SG® Star 1	Slide Attachments		1
108	072627	M-SG® / Mini-SG® Special parallelometer insert	M-SG® Star 1	Slide Attachments		1
109	07000040	M-SG® Star 1 Duplicating aid G	M-SG® Star 1	Slide Attachments		1
110	07000041	M-SG® Star 2 Duplicating aid G	M-SG® Star 2	Slide Attachments		1
111	070222	Attachment tweezers	N/A	Slide Attachments		1
112	072502	Slide Attachment SG Duplicating aid G	Slide Attachment SG®	Slide Attachments		1
113	052164	Slide Attachment SG Mounting screw X	Slide Attachment SG®	Slide Attachments		1
114	070293	Slide Attachment SG Screwdriver insert	Slide Attachment SG®	Slide Attachments		6, 2nd indent
115	070566	Slide Attachment SG Transfer jig	Slide Attachment SG®	Slide Attachments		1
116	070221	Thomas spanner key	Slide Attachment SG®	Slide Attachments		6, 2nd indent
117	072505	Tecnoroach Activator	Tecnoroach	Slide Attachments		1
118	072507	Tecnoroach Parallelometer insert	Tecnoroach	Slide Attachments		1

First Name / Name	Function	Date	Signature
Markus Blümli	Product Manager	15.12.2020	
Matthias Walther	Director of Development	17.12.2020	
Remi Meier	Product Safety Officer	25.01.2021	

Change Control:

Version	Date	Description of the Change	Reason of the Change
Version 1	14.10.2020	Devices reclassified from NOMED to Class I devices.	Review of classification of devices.
Version 2	30.11.2020/dym	1) Change of class and MDD rules for class IIa/IIb articles that are now in class I. 2) Change of classes and MDD rules for the articles that are now in NoMed (Spare Part) class. 3) Deletion of the NoMed and NoMed (Spare Part) articles. 4) Grouping of Class I articles in a single list of articles.	1) Änderungsantrag MD5-2943 2) Änderungsantrag MD5-3008 3) NoMed class articles must not be in the Declarations of Conformity. 4) Provides to have a single list with all class I articles.
	08.12.2020/dym	Deletion of the disinvested products	After verification of the list by mbl and after checking in SAP.

Valid for the project and/or the product(s): Review Declaration of conformity Class I according MDD

1. Laws for medical devices

The actual laws for medical devices are on CL 4.101 ("Gesetzessammlung Teil 2")

2. Standards and norms for medical devices

Based on SNV Service

No	Code	Norm	Title	Issue date	Valid
1	SN EN ISO	9001	Quality management systems – Requirements	2015-09	<input checked="" type="checkbox"/>
2	SN EN ISO	14001	Environmental Management System – Requirements with guidance for use	2015-09	<input checked="" type="checkbox"/>
3	SN EN ISO	13485	Medical devices, Quality management systems, Requirements for Regulatory purposes	2016-03	<input checked="" type="checkbox"/>
			Corrigendum AC	2020-04	
4	SN EN ISO	14971	Medical devices - Application of risk management to medical devices	2012-09	<input checked="" type="checkbox"/>
5	SN EN ISO	15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2017-02	<input checked="" type="checkbox"/>
6	SN EN	1041+A1	Information supplied by the manufacturer of medical devices	2013-10	<input checked="" type="checkbox"/>
7	SN EN ISO/IEC	17050-1	Conformity assessment - Supplier's declaration of conformity - Part 1: General requirements	2010-08	<input checked="" type="checkbox"/>
8	SN EN ISO/IEC	17050-2	Conformity assessment - Supplier's declaration of conformity - Part 2: Supporting documentation	2004-11	<input checked="" type="checkbox"/>
9	IEC	62366-1	Medical devices - Part 1: Application of usability engineering to medical devices	2015-02	<input type="checkbox"/>
			Technical Corrigendum	2016-07	
	SN EN	62366+A1	Medical devices - Part 1: Application of usability engineering to medical devices	2016-05	
10	SN EN ISO	17664	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices	2018-04	<input checked="" type="checkbox"/>
11	SN EN	1639	Dentistry - Medical devices for dentistry - Instruments	2010-03	<input type="checkbox"/>
12	SN EN	1640	Dentistry - Medical devices for dentistry - Equipment	2010-03	<input type="checkbox"/>
13	SN EN	1641	Dentistry - Medical devices for dentistry - Materials	2010-03	<input type="checkbox"/>
14	SN EN ISO	12836	Dentistry - Digitizing devices for CAD/CAM systems for indirect dental restorations - Test methods for assessing accuracy	2015-12	<input type="checkbox"/>
15	SN EN	10204	Metallic products - Types of inspection documents	2004-12	<input type="checkbox"/>
16	ISO	22674	Dentistry - Metallic materials for fixed and removable restorations and appliances	2016-01	<input checked="" type="checkbox"/>
17	SN EN ISO	10477	Dentistry - Polymer-based crown and veneering materials	2019-01	<input type="checkbox"/>
18	ISO	9693-1	Dentistry - Compatibility testing - Part 1: Metal-ceramic systems	2012-02	<input type="checkbox"/>
19	SN EN ISO	9333	Dentistry – Brazing materials	2006-10	<input type="checkbox"/>
20	SN EN ISO	28319	Dentistry - Laser welding and filler materials	2018-11	<input type="checkbox"/>

No	Code	Norm	Title	Issue date	Valid
21	ASTM	F67	Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700) Titan Grad 1(1083)/2 KV(780)/3(720)/4(721)/4 KV(725)/4 KV Dolder(1082)/4 CP4 low iron(1273)/4B ISO 5832-2(977)/Hannibal(976)	2013	<input checked="" type="checkbox"/>
22	ISO	5832-2	Implants for surgery - Metallic materials - Part 2: Unalloyed titanium Titan Grad 2(556)/2 KV(780)/3(720)/4(721)	2018-03	<input checked="" type="checkbox"/>
23	ASTM	F136	Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401) Syntax(555)/TiAl6V4 ELI(555)/Titan64(555)/Titan Grade 5(555)/Grade 23(555)/Certain(995)	2013	<input checked="" type="checkbox"/>
24	ASTM	B348	Standard Specification for Titanium and Titanium Alloy Bars and Billets Titan Grade 36/Ti45Nb (1228)	2013	<input type="checkbox"/>
25	ASTM	F899-19	Standard Specification for Wrought Stainless Steels for Surgical Instruments	2019	<input checked="" type="checkbox"/>
26	ASTM	F2820	Standard Specification for Polyetherketoneketone (PEKK) Polymers for Surgical Implant Applications	2012	<input type="checkbox"/>
27	SN EN ISO	7153-1	Surgical instruments - Materials - Part 1: Metals	2016-12	<input type="checkbox"/>
28	SN EN	10088-3	Stainless steels - Part 3: Technical delivery conditions for semi-finished products, bars, rods, wire, sections and bright products of corrosion resisting steels for general purposes 1.4435 (stainless steel: Medstahl, Chr Spezial 35)(1028)	2014-12	<input checked="" type="checkbox"/>
29	ASTM	F75	Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)	2018	<input type="checkbox"/>
30	ASTM	F799	Standard Specification for Cobalt-28Chromium-6Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)	2019	<input type="checkbox"/>
31	ASTM	F1537	Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)	2011	<input type="checkbox"/>
32	ISO	5832-4	Implants for surgery - Metallic materials - Part 4: Cobalt-chromium-molybdenum casting alloy	2014-09	<input type="checkbox"/>
33	ISO	5832-12	Implants for surgery - Metallic materials - Part 12: Wrought cobalt-chromium-molybdenum alloy	2019-02	<input type="checkbox"/>
34	ISO	13356	Implants for surgery -- Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)	2015-09	<input type="checkbox"/>
35	SN EN ISO	18064	Thermoplastic elastomers - Nomenclature and abbreviated terms	2015-02	<input type="checkbox"/>
36	SN EN ISO	1797	'Dentistry - Shanks for rotary and oscillating instruments	2017-09	<input checked="" type="checkbox"/>
37	SN EN ISO	6872	Dentistry - Ceramic materials	2015-09	<input type="checkbox"/>
			Amendment A1	2018-10	
38	ISO	5832-3	Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy	2016-10	<input checked="" type="checkbox"/>

3. Standards and norms for testing medical devices

No	Code	No	Title	Issue date	Valid
1	ASTM	D638	Standard Test Method for Tensile Properties of Plastics	2014	<input type="checkbox"/>
2	ASTM	D790-17	Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials	2017	<input type="checkbox"/>
3	ASTM	B265-15	Standard Specification for Titanium and Titanium Alloy Strip, Sheet, and Plate	2015	<input type="checkbox"/>
4	DIN	51007	Thermal analysis - Differential thermal analysis (DTA) and differential scanning calorimetry (DSC) - General Principles	2019-04	<input type="checkbox"/>
5	DIN	51045-1	Determination of the thermal expansion of solids - Part 1; Basic rules (WAK)	2005-08	<input type="checkbox"/>
6	ISO	6892-1	Metallic materials - Tensile testing - Part 1: Method of test at room temperature	2016-06	<input type="checkbox"/>
7	ISO	10271	Dentistry - Corrosion test methods for metallic materials (edition 2)	2011-08	<input type="checkbox"/>
8	SN EN ISO	6507-1	Metallic materials - Vickers hardness test - Part 1: Test method	2018-08	<input type="checkbox"/>
9	ISO	7405	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry	2018-10	<input checked="" type="checkbox"/>
10	ISO	7491	Dental materials - Determination of colour stability	2000-09	<input type="checkbox"/>
11	SN EN ISO	10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2010-03	<input checked="" type="checkbox"/>
			Corrigendum AC	2010-09	
12	SN EN ISO	10993-3	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	2014-12	<input type="checkbox"/>
13	SN EN ISO	10993-5	Biological evaluation of medical devices -Part 5: Tests for in vitro cytotoxicity	2009-11	<input checked="" type="checkbox"/>
14	SN EN ISO	10993-6	Biological evaluation of medical devices. Tests for local effects after implantation	2017-05	<input type="checkbox"/>
15	SN EN ISO	10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2013-12	<input type="checkbox"/>
16	SN EN ISO	10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	2018-10	<input type="checkbox"/>
17	SN EN ISO	10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	2012-09	<input type="checkbox"/>
18	SN EN ISO	10993-13	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices	2010-09	<input type="checkbox"/>
19	SN EN ISO	10993-14	Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics	2009-08	<input type="checkbox"/>
20	SN EN ISO	10993-15	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys	2009-11	<input type="checkbox"/>
21	SN EN ISO	10993-17	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances	2009-08	<input type="checkbox"/>
22	SN EN ISO	10993-18	Biological evaluation of medical devices - Part 18: Chemical characterization of materials	2009-08	<input type="checkbox"/>
23	ISO	14801	Dentistry - Implants - Dynamic loading test for endosseous dental implants	2016-11	<input type="checkbox"/>
24	SN EN ISO	20795-1	Dentistry - Base polymers, Part 1: Denture base polymers	2013-05	<input type="checkbox"/>
25	SN EN ISO	20795-2	Dentistry - Base polymers - Part 2: Orthodontic base polymers	2013-05	<input type="checkbox"/>


Validity for the project and/or the product is confirmed by x

Approval

Stefan Krebs
 Development Engineer

Datum: 7.10.2020 Visum: 

Remi Meier
 Head of Quality Management

Datum: 7.10.2020 Visum: 

4. Änderungsprotokoll

Eine erforderliche Schulung erfolgt durch den Prozesseigner mittels FO 6.301 „Schulungsnachweis für interne Schulung“. Das ausgefüllte Formular wird im HR als Nachweis archiviert. Für die Inkraftsetzung des Dokuments ist die Schulung rasch möglichst durchzuführen.

Alte Version	Änderungsdatum	Seite	Pos. / Punkt	Beschreibung der Änderung	Begründung der Änderung	Antragsteller	Schulung notwendig ¹⁾ Schulung nicht notwendig ²⁾
6	14.09.2020	alle	alle	Änderungen gem. AEA DA5-3064.	Änderungen am Normenabo. Schulung nicht notwendig, da die betreffenden Bereiche zu Normenupdates via E-Mail informiert werden. Neue Vorlage von FO 2323 wird per Inkraftsetzungsdatum publiziert.	jawe	<input type="checkbox"/> <input checked="" type="checkbox"/>

1) Datum der durchgeführten Schulung: _____

2) Falls keine Schulung notwendig ist, bitte im Änderungsprotokoll begründen: