CENDRES+ MÉTAUX

CE-Konformitätserklärung
CE-Déclaration de Conformité
EC-Declaration of Conformity

FO 00001956 Ausgabe 04
Erstellt: MQMA/rme Visum:
Geprüft: MQMA/jka Visum
Freigabe MERA/asp Visum:
Ausgabe-Datum: 25.03.2019

Wir, die Firma	Nous, la maison	We, the company
	Cendres+Métaux SA **Rue de Boujean 122** **CH-2501 Biel/Bienne**	
Bevollmächtigter	Mandataire	Authorized Representative
	Cendres+Métaux France SAS **Les petites Buffeteries** **F-49124 St-Barthélémy d'Anjou**	
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
Wurzelstifte und Wurzelanker gemäss beiliegender Liste	**Tenons et ancrages radiculaires** selon liste annexée	**Root chanal posts and root chanal anchors** according to attached list
	List_CM-RootChanals LDP-KE4 Version 7	
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 Root Chanal Posts and Anchors Edition 5	
Klassifizierung gemäss Anhang IX, 93/42/EWG: vergl. beiliegende Liste	**Classification** selon l'annexe IX, 93/42/CEE: Cf. liste annexée des produits	**Classification** according to annex IX, 93/42/EEC: see attached list of products
	List_CM-RootChanals LDP-KE4 Version 7	
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:	**Organisme notifié:** Classe I: Pas d'organisme notifié nécessaire. Autres classes:	**Notified Body:** Class I: No notified body needed. All other classes:
mdc medical device certification GmbH, Kriegerstraße 6, 70191 Stuttgart / Germany (CE 0483)		
Gültigkeit	**Validité** 2024-04-30	**Validity**
Änderungen: Änderungsantrag MD5-2943,	**Modifications:** demande modification MD5-2943, MD5-3008	**Changes:** change request MD5-2943, MD5-3008
Diese Konformitätserklärung wird mit den folgenden Unterschriften beglaubigt:	Cette déclaration de conformité est certifiée par les signatures suivantes:	This declaration is certified by the following signatures:

Biel/Bienne, 2021-01-25

Bibiana Gamper
Director of Quality & Regulatory

Remi Meier
Product Safety Officer

#	Catalog Number	Product Name	Device group	Family	Class MDD	Rule MDD
1	05003194	CM root canal post Adhesive head C (Size 1)	CM Root Canal Posts	Root canal posts	IIa	8, 1st indent
2	05003219	CM root canal post Adhesive head C (Size 1) (with cement flow-off groove)	CM Root Canal Posts	Root canal posts	IIa	8, 1st indent
3	05003195	CM root canal post Adhesive head C (Size 2)	CM Root Canal Posts	Root canal posts	IIa	8, 1st indent
4	05003226	CM root canal post Adhesive head C (Size 2) (with cement flow-off groove)	CM Root Canal Posts	Root canal posts	IIa	8, 1st indent
5	05003202	CM root canal post Adhesive head C (Size 3)	CM Root Canal Posts	Root canal posts	IIa	8, 1st indent
6	05003234	CM root canal post Adhesive head C (Size 3) (with cement flow-off groove)	CM Root Canal Posts	Root canal posts	IIa	8, 1st indent
7	05003210	CM root canal post Adhesive head C (Size 4)	CM Root Canal Posts	Root canal posts	IIa	8, 1st indent
8	05003242	CM root canal post Adhesive head C (Size 4) (with cement flow-off groove)	CM Root Canal Posts	Root canal posts	IIa	8, 1st indent
9	05003211	CM root canal post Adhesive head C (Size 5)	CM Root Canal Posts	Root canal posts	IIa	8, 1st indent
10	05003250	CM root canal post Adhesive head C (Size 5) (with cement flow-off groove)	CM Root Canal Posts	Root canal posts	IIa	8, 1st indent
11	05003584	CM root canal post Flat head T (Size 1) (with cement flow-off groove)	CM Root Canal Posts	Root canal posts	IIa	8, 1st indent
12	05003585	CM root canal post Flat head T (Size 2) (with cement flow-off groove)	CM Root Canal Posts	Root canal posts	IIa	8, 1st indent
13	05003586	CM root canal post Flat head T (Size 3) (with cement flow-off groove)	CM Root Canal Posts	Root canal posts	IIa	8, 1st indent
14	05003587	CM root canal post Flat head T (Size 4) (with cement flow-off groove)	CM Root Canal Posts	Root canal posts	IIa	8, 1st indent
15	05003588	CM root canal post Flat head T (Size 5) (with cement flow-off groove)	CM Root Canal Posts	Root canal posts	IIa	8, 1st indent
16	072328	CM root canal posts Root canal drill (Blue) Post size 4	CM Root Canal Posts	Root canal posts	IIa	6, general
17	072329	CM root canal posts Root canal drill (Green) Post size 5	CM Root Canal Posts	Root canal posts	IIa	6, general
18	072327	CM root canal posts Root canal drill (Red) Post size 3	CM Root Canal Posts	Root canal posts	IIa	6, general
19	072326	CM root canal posts Root canal drill (White) Post size 1	CM Root Canal Posts	Root canal posts	IIa	6, general
20	072321	CM root canal posts Root canal drill (Yellow) Post size 2	CM Root Canal Posts	Root canal posts	IIa	6, general
21	072330	Root canal drill	CM Root Canal Posts	Root canal posts	IIa	6, general
22	051904	Basic set big	Dalbo®-Rotex	Root canal posts	IIa	8, 1st indent
23	072474	Dalbo®-Rotex by Dr. Dalla Bona Face cutting drill (Yellow) Anchor size 2	Dalbo®-Rotex	Root canal posts	IIa	8, 1st indent
24	051869	Dalbo®-Rotex by Dr. Dalla Bona Male part T (Size 1)	Dalbo®-Rotex	Root canal posts	IIa	8, 1st indent
25	051870	Dalbo®-Rotex by Dr. Dalla Bona Male part T (Size 2)	Dalbo®-Rotex	Root canal posts	IIa	8, 1st indent
26	070499	Dalbo®-Rotex by Dr. Dallla Bona Face cutting drill (White) Anchor size 1	Dalbo®-Rotex	Root canal posts	IIa	6, general
27	072473	Dalbo®-Rotex by Prof. Brunner Face cutting drill (Yellow) Anchor size 2	Dalbo®-Rotex	Root canal posts	IIa	6, general
28	051871	Dalbo®-Rotex by Prof. Brunner Male part T (Size 1)	Dalbo®-Rotex	Root canal posts	IIa	8, 1st indent
29	051872	Dalbo®-Rotex by Prof. Brunner Male part T (Size 2)	Dalbo®-Rotex	Root canal posts	IIa	8, 1st indent
30	051868	Dalbo®-Rotex Female part G	Dalbo®-Rotex	Root canal posts	IIa	8, 1st indent
31	051864	Dalbo®-Rotex GT (Size 1) by Dr. Dalla Bona	Dalbo®-Rotex	Root canal posts	IIa	8, 1st indent
32	051866	Dalbo®-Rotex GT (Size 1) by Prof. Brunner	Dalbo®-Rotex	Root canal posts	IIa	8, 1st indent
33	051865	Dalbo®-Rotex GT (Size 2) by Dr. Dalla Bona	Dalbo®-Rotex	Root canal posts	IIa	8, 1st indent
34	051867	Dalbo®-Rotex GT (Size 2) by Prof. Brunner	Dalbo®-Rotex	Root canal posts	IIa	8, 1st indent
35	070481	CM root canal posts Post gauge Post size 1-5	Mooser Root Canal Posts	Root canal posts	IIa	6, general
36	05003505	Root canal post Mooser Adhesive head C (Size 1)	Mooser Root Canal Posts	Root canal posts	IIa	8, 1st indent
37	05003506	Root canal post Mooser Adhesive head C (Size 2)	Mooser Root Canal Posts	Root canal posts	IIa	8, 1st indent

38	05003507	Root canal post Mooser Adhesive head C (Size 3)	Mooser Root Canal Posts	Root canal posts	IIa	8, 1st indent
39	05003509	Root canal post Mooser Adhesive head C (Size 4)	Mooser Root Canal Posts	Root canal posts	IIa	8, 1st indent
40	05003589	Root canal post Mooser Flat head T (Size 1)	Mooser Root Canal Posts	Root canal posts	IIa	8, 1st indent
41	05003590	Root canal post Mooser Flat head T (Size 2)	Mooser Root Canal Posts	Root canal posts	IIa	8, 1st indent
42	05003591	Root canal post Mooser Flat head T (Size 3)	Mooser Root Canal Posts	Root canal posts	IIa	8, 1st indent
43	05003592	Root canal post Mooser Flat head T (Size 4)	Mooser Root Canal Posts	Root canal posts	IIa	8, 1st indent
44	072317	Root canal posts Mooser Pilot reamer (Blue) Post size 4	Mooser Root Canal Posts	Root canal posts	IIa	6, general
45	072316	Root canal posts Mooser Pilot reamer (Red) Post size 3	Mooser Root Canal Posts	Root canal posts	IIa	6, general
46	072314	Root canal posts Mooser Pilot reamer (White) Post size 1	Mooser Root Canal Posts	Root canal posts	IIa	6, general
47	072315	Root canal posts Mooser Pilot reamer (Yellow) Post size 2	Mooser Root Canal Posts	Root canal posts	IIa	6, general
48	070483	Root canal posts Mooser Post gauge Post size 1-4	Mooser Root Canal Posts	Root canal posts	IIa	6, general
49	072313	Root canal posts Mooser Root canal drill (Blue) Post size 4	Mooser Root Canal Posts	Root canal posts	IIa	6, general
50	072312	Root canal posts Mooser Root canal drill (Red) Post size 3	Mooser Root Canal Posts	Root canal posts	IIa	6, general
51	072310	Root canal posts Mooser Root canal drill (White) Post size 1	Mooser Root Canal Posts	Root canal posts	IIa	6, general
52	072311	Root canal posts Mooser Root canal drill (Yellow) Post size 2	Mooser Root Canal Posts	Root canal posts	IIa	6, general
53	MD.200004442	MP-Post MP auxiliary drill	MP Post	Root canal posts	IIa	6, general
54	MD.200004436	MP-Post MP root canal drill	MP Post	Root canal posts	IIa	6, general
55	MD.200004323	MP-Post Retentive K blue Size 3	MP Post	Root canal posts	IIa	6, general
56	MD.200004332	MP-Post Retentive K green Size 4	MP Post	Root canal posts	IIa	6, general
57	MD.200004314	MP-Post Retentive K red Size 2	MP Post	Root canal posts	IIa	6, general
58	MD.200004305	MP-Post Retentive K yellow Size 1	MP Post	Root canal posts	IIa	6, general
59	MD.200004451	MP-Post root canal drill blue Size 3	MP Post	Root canal posts	IIa	6, general
60	MD.200004455	MP-Post root canal drill green Size 4	MP Post	Root canal posts	IIa	6, general
61	MD.200004447	MP-Post root canal drill red Size 2	MP Post	Root canal posts	IIa	6, general
62	MD.200004441	MP-Post root canal drill yellow Size 1	MP Post	Root canal posts	IIa	6, general
63	MD.200004320	MP-Post Standard K blue Size 3	MP Post	Root canal posts	IIa	6, general
64	MD.200004329	MP-Post Standard K green Size 4	MP Post	Root canal posts	IIa	6, general
65	MD.200004311	MP-Post Standard K red Size 2	MP Post	Root canal posts	IIa	6, general
66	MD.200004302	MP-Post Standard K yellow Size 1	MP Post	Root canal posts	IIa	6, general
67	MD.200004319	MP-Post X blue Size 3	MP Post	Root canal posts	IIa	7, general
68	MD.200004328	MP-Post X green Size 4	MP Post	Root canal posts	IIa	7, general
69	MD.200004310	MP-Post X red Size 2	MP Post	Root canal posts	IIa	7, general
70	MD.200004301	MP-Post X yellow Size 1	MP Post	Root canal posts	IIa	7, general
71	MD.200004454	Pirec root canal drill blue Size 3	Pirec	Root canal posts	IIa	6, general
72	MD.200004458	Pirec root canal drill green Size 4	Pirec	Root canal posts	IIa	6, general
73	MD.200004450	Pirec root canal drill red Size 2	Pirec	Root canal posts	IIa	6, general
74	MD.200004446	Pirec root canal drill yellow Size 1	Pirec	Root canal posts	IIa	6, general
75	MD.200004317	Pirec T blue Size 3	Pirec	Root canal posts	IIa	8, 1st indent
76	MD.200004326	Pirec T green Size 4	Pirec	Root canal posts	IIa	8, 1st indent

77	MD.200004308	Pirec T red Size 2	Pirec	Root canal posts	IIa	8, 1st indent
78	070295	Rotex / Dalbo®-Rotex Face cutting drill (White) Anchor size 1	Rotex®	Root canal posts	IIa	6, general
79	070380	Rotex / Rotex-RD / Dalbo®-Rotex Root canal drill (White) Anchor size 1	Rotex®	Root canal posts	IIa	8, 1st indent
80	070381	Rotex / Rotex-RD / Dalbo®-Rotex Root canal drill (Yellow) Anchor size 2	Rotex®	Root canal posts	IIa	8, 1st indent
81	070298	Rotex / Rotex-RD / Dalbo®-Rotex Root canal reamer (White) Anchor size 1	Rotex®	Root canal posts	IIa	6, general
82	070299	Rotex / Rotex-RD / Dalbo®-Rotex Root canal reamer (Yellow) Anchor size 2	Rotex®	Root canal posts	IIa	8, 1st indent
83	070382	Rotex / Rotex-RD Root canal drill (Red) Anchor size 3	Rotex®	Root canal posts	IIa	6, general
84	070300	Rotex / Rotex-RD Root canal reamer (Red) Anchor size 3	Rotex®	Root canal posts	IIa	6, general
85	051497	Rotex Basic set	Rotex®	Root canal posts	IIa	8, 1st indent
86	070297	Rotex Face cutting drill (Red) Anchor size 3	Rotex®	Root canal posts	IIa	6, general
87	070296	Rotex Face cutting drill (Yellow) Anchor size 2	Rotex®	Root canal posts	IIa	6, general
88	051289	Rotex T Size 1	Rotex®	Root canal posts	IIa	8, 1st indent
89	051290	Rotex T Size 2	Rotex®	Root canal posts	IIa	8, 1st indent
90	051291	Rotex T Size 3	Rotex®	Root canal posts	IIa	8, 1st indent
91	055236	Rotex-RD Basic set	Rotex®-RD	Root canal posts	IIa	8, 1st indent
92	072472	Rotex-RD Face cutting drill (Red) Anchor size 3	Rotex®-RD	Root canal posts	IIa	6, general
93	072470	Rotex-RD Face cutting drill (White) Anchor size 1	Rotex®-RD	Root canal posts	IIa	6, general
94	072471	Rotex-RD Face cutting drill (Yellow) Anchor size 2	Rotex®-RD	Root canal posts	IIa	6, general
95	055195	Rotex-RD T Size 1	Rotex®-RD	Root canal posts	IIa	8, 1st indent
96	055196	Rotex-RD T Size 2	Rotex®-RD	Root canal posts	IIa	8, 1st indent
97	055197	Rotex-RD T Size 3	Rotex®-RD	Root canal posts	IIa	8, 1st indent

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 2	01.02.2016	Integration of all spare parts in the lists (no spare part articles on the list of Bars)	spare parts are in al points of veiw equivalent to the rest of articles
Version 2	11.02.2016	Integration of all products on demand in this list (no articles)	products on demand are in all points of view equal to the rest of articles
Version 3	28.06.2019 / skr	Article 070481 and 070483: Reclassification from Class I => class IIa rule 6 Article 070298, 070299 und 070300: Reclassification from Class I => class IIa rule 6	Reclassification from Class I => class IIa rule 6 (Change request MD5-2678)
Version 4	09.04.2020 / mast	Articles from position 78 to 100 (version 4) enclosed as new sales articles.	Packaging size adapted as part of change request MD5-2963. Assignment of new article numbers in terms of traceability ensurance.
Version 5	12.06.2020 / bga	Basis ist die "Device Master List". Produte die im SAP Status Desinvestiert haben wurden von der Liste entfernt.	Im Rahmen des NB Wechsels auf mdc werden die Produktlisten überprüft.
Version 6	30.06.2020/ bga	Art. 05003589, 05003590, 05003591, 05003592 - Name of Device corrected. Old: Root Canal post Mooser Adhesive head T --> correct: Root Canal post Mooser **Flat** head T	correction of the device name.

Version 7	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): Root Canal Posts and Anchors (KE4)

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	No	Title	Issue date	Valid
1	SN EN ISO	9001	Quality management systems – Requirements	2015-09	☐
2	SN EN ISO	14001	Environmental Management System	2015-09	☐
3	SN EN ISO	13485	Medical devices, Quality management systems, Requirements for Regulatory purposes	2016-03	☒
4	SN EN ISO	14971	Medical devices - Application of risk management to medical devices	2012-09	☒
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	☒
6	SN EN	1041+A1	Information supplied by the manufacturer of medical devices	2013-10	☒
7	SN EN ISO/IEC	17050-1	Conformity assessment - Supplier's declaration of conformity - Part 1: General requirements	2010-08	☒
8	SN EN ISO/IEC	17050-2	Conformity assessment - Supplier's declaration of conformity - Part 2: Supporting documentation	2004-11	☒
9	IEC	62366-1	Medical devices - Part 1: Application of usability engineering to medical devices	2015-02	☒
			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	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable devices	2018-04	☒
11	SN EN	1639	Dentistry - Medical devices for dentistry - Instruments	2010-03	☐
12	SN EN	1640	Dentistry - Medical devices for dentistry - Equipment	2010-03	☐
13	SN EN	1641	Dentistry - Medical devices for dentistry - Materials	2010-03	☐
14	SN EN ISO	12836	Dentistry - Digitizing devices for CAD/CAM systems for indirect dental restorations - Test methods for assessing accuracy	2015-12	☐
15	SN EN	10204	Metallic products - Types of inspection documents	2004-12	☐
16	ISO	22674	Dentistry - Metallic materials for fixed and removable restorations and appliances	2016-01	☒
17	SN EN ISO	4049	Dentistry -- Polymer-based restorative materials	2010-03	☐
18	SN EN ISO	10477	Dentistry -- Polymer-based crown and bridge materials	2005-03	☐
19	ISO	9693-1	Dentistry - Compatibility testing - Part 1: Metal-ceramic systems	2012-02	☐
20	SN EN ISO	9333	Dentistry – Brazing materials	2006-10	☐
21	SN EN ISO	28319	Dentistry - Laser welding	2010-08	☐

No	Code	No	Title	Issue date	Valid
22	ASTM	F 67	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	☒
23	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	☒
24	ASTM	F 136	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	☐
25	ASTM	B 348	Standard Specification for Titanium and Titanium Alloy Bars and Billets Titan Grade 36/Ti45Nb (1228)	2013	☐
26	ASTM	F 899-12b	Standard Specification for Wrought Stainless Steels for Surgical Instruments	2012	☒
27	ASTM	F2820	Standard Specification for Polyetherketoneketone (PEKK) Polymers for Surgical Implant Applications	2012	☐
28	SN EN ISO	7153-1	Surgical instruments - Materials - Part 1: Metals	2016-12	☐
29	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	☒
30	ASTM	F75	Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)	2012	☐
31	ASTM	F799	Standard Specification for Cobalt-28Chromium-6Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)	2011	☐
32	ASTM	F1537	Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)	2011	☐
33	ISO	5832-4	Implants for surgery - Metallic materials - Part 4: Cobalt-chromium-molybdenum casting alloy	2014-09	☐
34	ISO	5832-12	Implants for surgery - Metallic materials - Part 12: Wrought cobalt-chromium-molybdenum alloy	2007-05	☐
35	ISO	13356	Implants for surgery -- Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)	2015-09	☐
36	SN EN ISO	18064	Thermoplastic elastomers - Nomenclature and abbreviated terms	2015-02	☐
37	SN EN ISO	1797-1	Dentistry - Shanks for rotary instruments - Part 1: Shanks made of metals	2017-09	☒
38	SN EN ISO	6872	Dentistry - Ceramic materials	2015-09	☒
39	ISO	5832-3	Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy	2016-10	☐

3. Standards and norms for testing medical devices

No	Code	No	Title	Issue date	Valid
1	ASTM	D 638	Standard Test Method for Tensile Properties of Plastics	2014	☐
2	ASTM	D 790-17	Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials	2017	☐
3	ASTM	B 265-15	Standard Specification for Titanium and Titanium Alloy Strip, Sheet, and Plate	2015	☐
4	DIN	51004	Thermal analysis; determination of melting temperatures of crystalline materials by differential thermal analysis	1994-06	☐
5	DIN	51045-1	Determination of the thermal expansion of solids - Part 1: Basic rules (WAK)	2005-08	☐
6	ISO	6892-1	Metallic materials - Tensile testing - Part 1: Method of test at room temperature	2016-06	☐
7	ISO	10271	Dentistry - Corrosion test methods for metallic materials (edition 2)	2011-08	☐
8	ISO	6507-1	Metallic materials - Vickers hardness test - Part 1: Test method (ISO 6507-1:2005)	2018-01	☐
9	ISO	7405	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry AMD 1: Positive control material	2008-12 2013-07	☒
10	ISO	7491	Dental materials -- Determination of colour stability	2000-09	☐
11	SN EN ISO	10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing AC	2010-03 2010-09	☒
12	SN EN ISO	10993-3	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	2014-12	☐
13	SN EN ISO	10993-5	Biological evaluation of medical devices -Part 5: Tests for in vitro cytotoxicity	2009-11	☐
14	SN EN ISO	10993-6	Biological evaluation of medical devices. Tests for local effects after implantation	2017-05	☐
15	SN EN ISO	10993-10	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity	2013-12	☐
16	SN EN ISO	10993-11	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	2009-08	☐
17	SN EN ISO	10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	2012-09	☐
18	SN EN ISO	10993-14	Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics	2009-08	☐
19	SN EN ISO	10993-15	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys	2009-11	☐
20	SN EN ISO	10993-18	Biological evaluation of medical devices - Part 18: Chemical characterization of materials	2009-08	☐
21	ISO	14801	Dentistry - Implants - Dynamic loading test for endosseous dental implants	2016-11	☐
22	SN EN ISO	20795-1	Dentistry - Base polymers, Part 1: Denture base polymers	2013-05	☐
23	SN EN ISO	20795-2	Dentistry - Base polymers - Part 2: Orthodontic base polymers	2013-05	☐

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

Approval

Manuel Stebinger
Development Engineer

Datum: 12.02.2019 Visum: M. Steb

Remi Meier
Head of Quality Management

Datum: 12.2.2019 Visum:

4. Änderungskontrolle

Ist eine Schulung erforderlich, hat der Prozesseigner die betroffenen Personen zu Schulen. Die Schulung ist mittels FO 6.301 „Nachweis interne Schulung" zu dokumentieren. Der Nachweis ist QMA zur Archivierung abzugeben.
Die Schulungen sind rasch möglichst durchzuführen da sonst die Änderung nicht durchgesetzt werden kann.

5. Änderungsprotokoll

Änderungs-Datum	Seite	Pos./ Punkt	Beschreibung der Änderung	Begründung der Änderung.	Antragsteller	Schulung notwendig [1]	Schulung nicht notwendig [2]
13.10.2017	alle	Alle	Neugestaltung des Formulars im Excel für einfachere Verwaltung und Sortierung	Neugestaltung des Formulars im Excel für einfachere Verwaltung und Sortierung Änderung ohne Schulungsbedarf, da Anwender an der Verbesserung beteiligt waren	ble	☐	☒
13.10.2017	Alle	alle	Einfügen der neuen Versionen von: - ISO 22674:2016-01 - ISO 1797-1:2017-05 - SN EN ISO 10993-6:2017-05 - ISO 14801:2016-11	Generelle Aktualisierung ohne Schulungsbedarf	ble	☐	☒
13.10.2018	N/A	N/A	Versionsänderung von 03 auf 04 wurde nicht dokumentiert	N/A	N/A	☐	☒
13.12.2018	alle	alle	Normenaktualisierung Layoutwechsel auf Word	Generelle Aktualisierung ohne Schulungsbedarf	jka	☐	☒

[1] Datum der durchgeführten Schulung:

[2] Falls keine Schulung notwendig ist, bitte im Änderungsprotokoll begründen.

CENDRES+ MÉTAUX

Non-significant changes (MDCG 2020-3) affecting the content of the Declarations of Conformity (DoC) issued under EU MDD 93/42/EEC

Change number – Description	Affected content
MD5-3639 EU-REP change	**Previous EU-REP:** Cendres+Métaux France SAS, Les petites Buffeteries, 49124 St-Barthélémy d'Anjou, France **New EU-REP:** QualRep Services B.V., Utrechtseweg 310 – Bldg B42, 6812 AR Arnhem, The Netherlands

Biel/Bienne, 11.10.2023

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Matthias Walther
Director of Quality & Regulatory
Cendres+Métaux SA

** Person responsible for compliance with the regulatory requirements MDR (EU) 2017/745 in accordance with Article 15.*