

Wir, die Firma

Nous, la maison

We, the company

Cendres+ Métaux SA
Rue de Boujean 122
CH-2501 Biel/Bienne

Bevollmächtigter

Mandataire
Cendres+ Métaux France SAS
Les petites Buffeteries
F-49124 St-Barthélémy d'Anjou

Authorized Representative

erklären hiermit in alleiniger
Verantwortung, dass die folgen-
den Produkte

déclarons sous notre seule
responsabilité que les produits
suivants

declare under our sole responsibility that
the following products

Dental-Werkstoffe

Matériaux dentaires

Dental materials

gemäss beiliegender Liste

selon liste annexée
List_CM-Alloys DCA01 Version 3

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 Dental Casting Alloys Edition 05

Klassifizierung gemäss
Anhang IX, 93/42/EWG:
vergl. beiliegende Liste

Classification selon
l'annexe IX, 93/42/CEE:
Cf. liste annexée des produits
List_CM-Alloys DCA01 Version 3

Classification according to
annex IX, 93/42/EEC:
see attached list of products

**Konformitätsbewertungs-
verfahren:**

**Procédure d'évaluation de la
conformité:**

Conformity assessment procedure:

93/42/EWG

93/42/CEE

93/42/EEC

Klasse I: Anhang VII

Classe I: Annexe VII

Class I: Annex VII

Übrige Klassen: Anhang II
(ohne Abschnitt 4)

Autres classes: Annexe II
(sans section 4)

All other classes: Annex II
(Without section 4)

Benannte Stelle:

Organisme notifié:

Notified Body:

Klasse I: Benannte Stelle nicht
erforderlich.

Classe I: Pas d'organisme notifié
nécessaire.

Class I: No notified body needed.

Übrige Klassen: MDC (CE 0483)

Autres classes: MDC (CE 0483)

All other classes: MDC (CE 0483)

Gültigkeit

Validité

Validity

Änderungen:

Modifications:

Changes:

Änderungsantrag DV5-2735

demande modification DV5-2735

change request DV5-2735

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, **2021-06-23**


Bibiana Gamper
Director of Quality & Regulatory


Remi Meier
Product Safety Officer

#	Catalog Number	Product Name	Device group	Family	Class MDD	Rule MDD
1	010923	BioEthic®	Alloys	Alloys	Ila	8, 1st indent
2	01050020	Ceradelta®	Alloys	Alloys	Ila	8, 1st indent
3	01050033	Ceradelta® 2	Alloys	Alloys	Ila	8, 1st indent
4	01050011	Cerapall® 2	Alloys	Alloys	Ila	8, 1st indent
5	01050016	Cerapall® 6	Alloys	Alloys	Ila	8, 1st indent
6	010922	DGVO8 H	Alloys	Alloys	Ila	8, 1st indent
7	01000112	Esteticor® Accurate 40	Alloys	Alloys	Ila	8, 1st indent
8	010614	Esteticor® Actual	Alloys	Alloys	Ila	8, 1st indent
9	010972	Esteticor® Avenir	Alloys	Alloys	Ila	8, 1st indent
10	011011	Esteticor® Biennor CF	Alloys	Alloys	Ila	8, 1st indent
11	01000108	Esteticor® Blancor	Alloys	Alloys	Ila	8, 1st indent
12	01000115	Esteticor® CC	Alloys	Alloys	Ila	8, 1st indent
13	010609	Esteticor® Cosmor H	Alloys	Alloys	Ila	8, 1st indent
14	010994	Esteticor® Ecologic	Alloys	Alloys	Ila	8, 1st indent
15	010617	Esteticor® Economic	Alloys	Alloys	Ila	8, 1st indent
16	010865	Esteticor® Ideal H	Alloys	Alloys	Ila	8, 1st indent
17	01000036	Esteticor® Implant 32	Alloys	Alloys	Ila	8, 1st indent
18	01000030	Esteticor® Implant 58	Alloys	Alloys	Ila	8, 1st indent
19	01000038	Esteticor® Implant 76	Alloys	Alloys	Ila	8, 1st indent
20	01000010	Esteticor® Lumina PF	Alloys	Alloys	Ila	8, 1st indent
21	01000083	Esteticor® N2	Alloys	Alloys	Ila	8, 1st indent
22	010898	Esteticor® NewStart	Alloys	Alloys	Ila	8, 1st indent
23	010620	Esteticor® Plus	Alloys	Alloys	Ila	8, 1st indent
24	010783	Esteticor® Prestige	Alloys	Alloys	Ila	8, 1st indent
25	010623	Esteticor® Special	Alloys	Alloys	Ila	8, 1st indent
26	01050023	V-Classic	Alloys	Alloys	Ila	8, 1st indent
27	01050017	V-Delta® SF	Alloys	Alloys	Ila	8, 1st indent
28	01050028	V-Delta® Special	Alloys	Alloys	Ila	8, 1st indent
29	01050001	V-Delta® alloy	Alloys	Alloys	Ila	8, 1st indent
30	01050032	V-Gnathos® Plus	Alloys	Alloys	Ila	8, 1st indent
31	01050010	Aurofluid® 2 PF	Alloys	Alloys	Ila	8, 1st indent
32	010636	Dentalor® 60	Alloys	Alloys	Ila	8, 1st indent

33	010641	Medior® 3	Alloys	Alloys	Ila	8, 1st indent
34	010646	Neocast® 3	Alloys	Alloys	Ila	8, 1st indent
35	010869	Opticast®	Alloys	Alloys	Ila	8, 1st indent
36	01050012	Pagalin® 2	Alloys	Alloys	Ila	8, 1st indent
37	01050024	Pagalinor® 2	Alloys	Alloys	Ila	8, 1st indent
38	010651	Pallorag® 33	Alloys	Alloys	Ila	8, 1st indent
39	01050022	Pontor® 2	Alloys	Alloys	Ila	8, 1st indent
40	01050021	Pontor® MPF	Alloys	Alloys	Ila	8, 1st indent
41	010654	Protor® 3	Alloys	Alloys	Ila	8, 1st indent
42	01050007	Solaro® 3	Alloys	Alloys	Ila	8, 1st indent
43	01000114	Solaro® 4	Alloys	Alloys	Ila	8, 1st indent
44	010675	Strator 3	Alloys	Alloys	Ila	8, 1st indent
45	01050026	Yellow Special	Alloys	Alloys	Ila	8, 1st indent
46	010875	S.G 700 Rod	Alloys	Alloys	Ila	8, 1st indent
47	010895	S.G 750 Rod	Alloys	Alloys	Ila	8, 1st indent
48	010916	S.G 810 Rod	Alloys	Alloys	Ila	8, 1st indent
49	010878	S.G 880 Rod	Alloys	Alloys	Ila	8, 1st indent
50	010974	S.G 920 Rod	Alloys	Alloys	Ila	8, 1st indent
51	010822	S.G 1030 Rod	Alloys	Alloys	Ila	8, 1st indent
52	010888	S.G 1055 Rod	Alloys	Alloys	Ila	8, 1st indent
53	010819	S.G 1080 Rod	Alloys	Alloys	Ila	8, 1st indent
54	01050030	S.G 1120 Rod	Alloys	Alloys	Ila	8, 1st indent
55	010826	S.G 1155 Coil	Alloys	Alloys	Ila	8, 1st indent
56	010918	S.W 1100 Stab	Alloys	Alloys	Ila	8, 1st indent
57	01050031	S.W 1125 Stab	Alloys	Alloys	Ila	8, 1st indent
58	01050039	LW N° 1	Alloys	Alloys	Ila	8, 1st indent
59	01050043	LW N° 2	Alloys	Alloys	Ila	8, 1st indent
60	01050040	LW N° 3	Alloys	Alloys	Ila	8, 1st indent
61	01050042	LW N° 4	Alloys	Alloys	Ila	8, 1st indent
62	01050041	LW N° 5	Alloys	Alloys	Ila	8, 1st indent
63	01050038	LW N° 6	Alloys	Alloys	Ila	8, 1st indent
64	01050044	LW N° 7	Alloys	Alloys	Ila	8, 1st indent
65	01050005	V-GNATHOS SUPRA	Alloys	Alloys	Ila	8, 1st indent
66	01050006	V 92	Alloys	Alloys	Ila	8, 1st indent
67	01050008	Solaro Special	Alloys	Alloys	Ila	8, 1st indent

68	01050019	V-Supragold	Alloys	Alloys	Ila	8, 1st indent
69	010644	Modulor 3	Alloys	Alloys	Ila	8, 1st indent
70	010652	Pallorag 35	Alloys	Alloys	Ila	8, 1st indent
71	01050009	Aurofluid 3	Alloys	Alloys	Ila	8, 1st indent
72	01050034	Ecodelta	Alloys	Alloys	Ila	8, 1st indent
73	010267	Elasticor wire Ø 1.15 mm	Alloys	Alloys	Ila	8, 1st indent
74	01000170	Ceradelta 2 - 01050033 (10g)	Alloys	Alloys	Ila	8, 1st indent
75	01000171	Ceradelta 2 - 01050033 (25g)	Alloys	Alloys	Ila	8, 1st indent
76	01000172	Ceradelta 2 - 01050033 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
77	01000173	Ceradelta 2 - 01050033 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
78	01000174	Ceradelta 2 - 01050033 (31.1g)	Alloys	Alloys	Ila	8, 1st indent
79	01000175	Esteticor® CC - 01000115 (10g)	Alloys	Alloys	Ila	8, 1st indent
80	01000176	Esteticor® CC - 01000115 (25g)	Alloys	Alloys	Ila	8, 1st indent
81	01000177	Esteticor® CC - 01000115 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
82	01000178	Esteticor® CC - 01000115 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
83	01000179	Esteticor® Plus - 010620 (10g)	Alloys	Alloys	Ila	8, 1st indent
84	01000180	Esteticor® Plus - 010620 (25g)	Alloys	Alloys	Ila	8, 1st indent
85	01000181	Esteticor® Plus - 010620 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
86	01000182	Esteticor® Plus - 010620 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
87	01000183	Esteticor® Plus - 010620 (31.1g)	Alloys	Alloys	Ila	8, 1st indent
88	01000184	Esteticor® N2 - 01000083 (10g)	Alloys	Alloys	Ila	8, 1st indent
89	01000185	Esteticor® N2 - 01000083 (25g)	Alloys	Alloys	Ila	8, 1st indent
90	01000186	Esteticor® N2 - 01000083 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
91	01000187	Esteticor® N2 - 01000083 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
92	01000188	Cerapall 6 - 01050016 (10g)	Alloys	Alloys	Ila	8, 1st indent
93	01000189	Cerapall 6 - 01050016 (25g)	Alloys	Alloys	Ila	8, 1st indent
94	01000190	Cerapall 6 - 01050016 (31.1g)	Alloys	Alloys	Ila	8, 1st indent
95	01000191	Esteticor® Implant 32 - 01000036 (10g)	Alloys	Alloys	Ila	8, 1st indent
96	01000192	Esteticor® Implant 32 - 01000036 (25g)	Alloys	Alloys	Ila	8, 1st indent
97	01000193	Esteticor® Implant 32 - 01000036 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
98	01000194	Esteticor® Implant 32 - 01000036 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
99	01000195	V-Delta Special - 01050028 (10g)	Alloys	Alloys	Ila	8, 1st indent
100	01000196	V-Delta Special - 01050028 (25g)	Alloys	Alloys	Ila	8, 1st indent
101	01000197	V-Delta Special - 01050028 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
102	01000198	V-Delta Special - 01050028 (30.0g)	Alloys	Alloys	Ila	8, 1st indent

103	01000199	V-Delta Special - 01050028 (31.1g)	Alloys	Alloys	Ila	8, 1st indent
104	01000200	V-Deltaloy - 01050001 (10g)	Alloys	Alloys	Ila	8, 1st indent
105	01000201	V-Deltaloy - 01050001 (25g)	Alloys	Alloys	Ila	8, 1st indent
106	01000202	V-Deltaloy - 01050001 (31.1g)	Alloys	Alloys	Ila	8, 1st indent
107	01000203	V-Delta SF - 01050017 (10g)	Alloys	Alloys	Ila	8, 1st indent
108	01000204	V-Delta SF - 01050017 (25g)	Alloys	Alloys	Ila	8, 1st indent
109	01000205	V-Delta SF - 01050017 (31.1g)	Alloys	Alloys	Ila	8, 1st indent
110	01000206	Estetikor® NewStart - 010898 (10g)	Alloys	Alloys	Ila	8, 1st indent
111	01000207	Estetikor® NewStart - 010898 (25g)	Alloys	Alloys	Ila	8, 1st indent
112	01000208	Estetikor® Blancor - 01000108 (10g)	Alloys	Alloys	Ila	8, 1st indent
113	01000209	Estetikor® Blancor - 01000108 (25g)	Alloys	Alloys	Ila	8, 1st indent
114	01000210	Estetikor® Blancor - 01000108 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
115	01000211	Estetikor® Blancor - 01000108 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
116	01000212	Estetikor® Blancor - 01000108 (31.1g)	Alloys	Alloys	Ila	8, 1st indent
117	01000213	Cerapall 2 - 01050011 (10g)	Alloys	Alloys	Ila	8, 1st indent
118	01000214	Cerapall 2 - 01050011 (25g)	Alloys	Alloys	Ila	8, 1st indent
119	01000215	Cerapall 2 - 01050011 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
120	01000216	Cerapall 2 - 01050011 (31.1g)	Alloys	Alloys	Ila	8, 1st indent
121	01000217	Estetikor® Biennor CF - 011011 (10g)	Alloys	Alloys	Ila	8, 1st indent
122	01000218	Estetikor® Biennor CF - 011011 (25g)	Alloys	Alloys	Ila	8, 1st indent
123	01000219	Estetikor® Biennor CF - 011011 (31.1g)	Alloys	Alloys	Ila	8, 1st indent
124	01000220	V-Classic - 01050023 (10g)	Alloys	Alloys	Ila	8, 1st indent
125	01000221	V-Classic - 01050023 (25g)	Alloys	Alloys	Ila	8, 1st indent
126	01000222	V-Classic - 01050023 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
127	01000223	V-Gnathos Plus - 01050032 (10g)	Alloys	Alloys	Ila	8, 1st indent
128	01000224	V-Gnathos Plus - 01050032 (25g)	Alloys	Alloys	Ila	8, 1st indent
129	01000225	V-Gnathos Plus - 01050032 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
130	01000226	V-Gnathos Plus - 01050032 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
131	01000227	V-Gnathos Plus - 01050032 (31.1g)	Alloys	Alloys	Ila	8, 1st indent
132	01000228	Estetikor® Implant 58 - 01000030 (10g)	Alloys	Alloys	Ila	8, 1st indent
133	01000229	Estetikor® Implant 58 - 01000030 (25g)	Alloys	Alloys	Ila	8, 1st indent
134	01000230	Estetikor® Implant 58 - 01000030 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
135	01000231	Estetikor® Implant 58 - 01000030 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
136	01000232	Estetikor® Implant 58 - 01000030 (31.1g)	Alloys	Alloys	Ila	8, 1st indent
137	01000233	Estetikor® Special - 010623 (10g)	Alloys	Alloys	Ila	8, 1st indent

138	01000234	Esteticor® Special - 010623 (25g)	Alloys	Alloys	Ila	8, 1st indent
139	01000235	Esteticor® Cosmor H - 010609 (10g)	Alloys	Alloys	Ila	8, 1st indent
140	01000236	Esteticor® Cosmor H - 010609 (25g)	Alloys	Alloys	Ila	8, 1st indent
141	01000237	Esteticor® Cosmor H - 010609 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
142	01000238	Esteticor® Cosmor H - 010609 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
143	01000239	Esteticor® Economic - 010617 (10g)	Alloys	Alloys	Ila	8, 1st indent
144	01000240	Esteticor® Economic - 010617 (25g)	Alloys	Alloys	Ila	8, 1st indent
145	01000241	Esteticor® Economic - 010617 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
146	01000242	Esteticor® Economic - 010617 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
147	01000243	Ceradelta - 01050020 (10g)	Alloys	Alloys	Ila	8, 1st indent
148	01000244	Ceradelta - 01050020 (25g)	Alloys	Alloys	Ila	8, 1st indent
149	01000245	Ceradelta - 01050020 (31.1g)	Alloys	Alloys	Ila	8, 1st indent
150	01000246	Esteticor® Avenir - 010972 (10g)	Alloys	Alloys	Ila	8, 1st indent
151	01000247	Esteticor® Avenir - 010972 (25g)	Alloys	Alloys	Ila	8, 1st indent
152	01000248	Esteticor® Avenir - 010972 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
153	01000249	Esteticor® Avenir - 010972 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
154	01000250	Esteticor® Actual - 010614 (10g)	Alloys	Alloys	Ila	8, 1st indent
155	01000251	Esteticor® Actual - 010614 (25g)	Alloys	Alloys	Ila	8, 1st indent
156	01000252	Esteticor® Actual - 010614 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
157	01000253	Esteticor® Actual - 010614 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
158	01000254	Esteticor® Lumina PF - 01000010 (10g)	Alloys	Alloys	Ila	8, 1st indent
159	01000255	Esteticor® Lumina PF - 01000010 (25g)	Alloys	Alloys	Ila	8, 1st indent
160	01000256	Esteticor® Lumina PF - 01000010 (31.1g)	Alloys	Alloys	Ila	8, 1st indent
161	01000257	Esteticor® Prestige - 010783 (10g)	Alloys	Alloys	Ila	8, 1st indent
162	01000258	Esteticor® Prestige - 010783 (25g)	Alloys	Alloys	Ila	8, 1st indent
163	01000259	Esteticor® Implant 76 - 01000038 (10g)	Alloys	Alloys	Ila	8, 1st indent
164	01000260	Esteticor® Implant 76 - 01000038 (25g)	Alloys	Alloys	Ila	8, 1st indent
165	01000261	Esteticor® Implant 76 - 01000038 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
166	01000262	Esteticor® Implant 76 - 01000038 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
167	01000263	Esteticor® Ecologic - 010994 (10g)	Alloys	Alloys	Ila	8, 1st indent
168	01000264	Esteticor® Ecologic - 010994 (25g)	Alloys	Alloys	Ila	8, 1st indent
169	01000265	Esteticor® Ideal H - 010865 (10g)	Alloys	Alloys	Ila	8, 1st indent
170	01000266	Esteticor® Ideal H - 010865 (25g)	Alloys	Alloys	Ila	8, 1st indent
171	01000267	Esteticor® Ideal H - 010865 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
172	01000268	Esteticor® Ideal H - 010865 (30.0g)	Alloys	Alloys	Ila	8, 1st indent

173	01000269	BioEthic - 010923 (10g)	Alloys	Alloys	Ila	8, 1st indent
174	01000270	BioEthic - 010923 (25g)	Alloys	Alloys	Ila	8, 1st indent
175	01000271	BioEthic - 010923 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
176	01000272	BioEthic - 010923 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
177	01000273	Esteticor® Accurate 40 - 01000112 (10g)	Alloys	Alloys	Ila	8, 1st indent
178	01000274	Esteticor® Accurate 40 - 01000112 (25g)	Alloys	Alloys	Ila	8, 1st indent
179	01000275	Esteticor® Accurate 40 - 01000112 (31.1g)	Alloys	Alloys	Ila	8, 1st indent
180	01000276	DGVO8 H - 010922 (10g)	Alloys	Alloys	Ila	8, 1st indent
181	01000277	DGVO8 H - 010922 (25g)	Alloys	Alloys	Ila	8, 1st indent
182	01000278	Pagalin 2 - 01050012 (10g)	Alloys	Alloys	Ila	8, 1st indent
183	01000279	Pagalin 2 - 01050012 (25g)	Alloys	Alloys	Ila	8, 1st indent
184	01000280	Protor 3 - 010654 (10g)	Alloys	Alloys	Ila	8, 1st indent
185	01000281	Protor 3 - 010654 (25g)	Alloys	Alloys	Ila	8, 1st indent
186	01000282	Protor 3 - 010654 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
187	01000283	Protor 3 - 010654 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
188	01000284	Protor 3 - 010654 (31.1g)	Alloys	Alloys	Ila	8, 1st indent
189	01000285	Neocast 3 - 010646 (10g)	Alloys	Alloys	Ila	8, 1st indent
190	01000286	Neocast 3 - 010646 (25g)	Alloys	Alloys	Ila	8, 1st indent
191	01000287	Neocast 3 - 010646 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
192	01000288	Neocast 3 - 010646 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
193	01000289	Neocast 3 - 010646 (31.1g)	Alloys	Alloys	Ila	8, 1st indent
194	01000290	Yellow Special - 01050026 (10g)	Alloys	Alloys	Ila	8, 1st indent
195	01000291	Yellow Special - 01050026 (25g)	Alloys	Alloys	Ila	8, 1st indent
196	01000292	Yellow Special - 01050026 (31.1g)	Alloys	Alloys	Ila	8, 1st indent
197	01000293	Pontor MPF - 01050021 (10g)	Alloys	Alloys	Ila	8, 1st indent
198	01000294	Pontor MPF - 01050021 (25g)	Alloys	Alloys	Ila	8, 1st indent
199	01000295	Pontor MPF - 01050021 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
200	01000296	Pontor MPF - 01050021 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
201	01000297	Pontor MPF - 01050021 (31.1g)	Alloys	Alloys	Ila	8, 1st indent
202	01000298	Medior 3 - 010641 (10g)	Alloys	Alloys	Ila	8, 1st indent
203	01000299	Medior 3 - 010641 (25g)	Alloys	Alloys	Ila	8, 1st indent
204	01000300	Medior 3 - 010641 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
205	01000301	Medior 3 - 010641 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
206	01000302	Dentalor 60 - 010636 (10g)	Alloys	Alloys	Ila	8, 1st indent
207	01000303	Dentalor 60 - 010636 (25g)	Alloys	Alloys	Ila	8, 1st indent

208	01000304	Dentalor 60 - 010636 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
209	01000305	Dentalor 60 - 010636 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
210	01000306	Pallorag 33 - 010651 (10g)	Alloys	Alloys	Ila	8, 1st indent
211	01000307	Pallorag 33 - 010651 (25g)	Alloys	Alloys	Ila	8, 1st indent
212	01000308	Solaro 3 - 01050007 (10g)	Alloys	Alloys	Ila	8, 1st indent
213	01000309	Solaro 3 - 01050007 (25g)	Alloys	Alloys	Ila	8, 1st indent
214	01000310	Solaro 3 - 01050007 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
215	01000311	Solaro 3 - 01050007 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
216	01000312	Solaro 3 - 01050007 (31.1g)	Alloys	Alloys	Ila	8, 1st indent
217	01000313	Strator 3 - 010675 (10g)	Alloys	Alloys	Ila	8, 1st indent
218	01000314	Strator 3 - 010675 (25g)	Alloys	Alloys	Ila	8, 1st indent
219	01000315	Strator 3 - 010675 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
220	01000316	Strator 3 - 010675 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
221	01000317	Aurofluid 2 PF - 01050010 (10g)	Alloys	Alloys	Ila	8, 1st indent
222	01000318	Aurofluid 2 PF - 01050010 (25g)	Alloys	Alloys	Ila	8, 1st indent
223	01000319	Aurofluid 2 PF - 01050010 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
224	01000320	Aurofluid 2 PF - 01050010 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
225	01000321	Aurofluid 2 PF - 01050010 (31.1g)	Alloys	Alloys	Ila	8, 1st indent
226	01000322	Solaro 4 - 01000114 (10g)	Alloys	Alloys	Ila	8, 1st indent
227	01000323	Solaro 4 - 01000114 (25g)	Alloys	Alloys	Ila	8, 1st indent
228	01000324	Solaro 4 - 01000114 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
229	01000325	Opticast - 010869 (10g)	Alloys	Alloys	Ila	8, 1st indent
230	01000326	Opticast - 010869 (25g)	Alloys	Alloys	Ila	8, 1st indent
231	01000327	Opticast - 010869 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
232	01000328	Opticast - 010869 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
233	01000329	Opticast - 010869 (31.1g)	Alloys	Alloys	Ila	8, 1st indent
234	01000330	Pagalinor 2 - 01050024 (10g)	Alloys	Alloys	Ila	8, 1st indent
235	01000331	Pagalinor 2 - 01050024 (25g)	Alloys	Alloys	Ila	8, 1st indent
236	01000332	Pontor 2 - 01050022 (10g)	Alloys	Alloys	Ila	8, 1st indent
237	01000333	Pontor 2 - 01050022 (25g)	Alloys	Alloys	Ila	8, 1st indent
238	01000334	V-Supragold - 01050019 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
239	01000335	Eco Delta - 01050034 (10g)	Alloys	Alloys	Ila	8, 1st indent
240	01000336	V-Gnathos Supra - 01050005 (10g)	Alloys	Alloys	Ila	8, 1st indent
241	01000337	V-92 - 01050006 (10g)	Alloys	Alloys	Ila	8, 1st indent
242	01000338	Solaro Special - 01050008 (10.0g)	Alloys	Alloys	Ila	8, 1st indent

243	01000339	Aurofluid 3 - 01050009 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
244	01000340	Aurofluid 3 - 01050009 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
245	01000341	Pallorag 35 - 010652 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
246	01000342	Pallorag 35 - 010652 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
247	01000343	Modulor 3 - 010644 (10.0g)	Alloys	Alloys	Ila	8, 1st indent
248	01000344	Modulor 3 - 010644 (30.0g)	Alloys	Alloys	Ila	8, 1st indent
249	01000345	S.G 750 - 010895 (1Stk)	Alloys	Alloys	Ila	8, 1st indent
250	01000346	S.W 1100 - 010918 (1Stk)	Alloys	Alloys	Ila	8, 1st indent
251	01000347	S.G 1080 - 010819 (1Stk)	Alloys	Alloys	Ila	8, 1st indent
252	01000348	S.G 810 - 010916 (1Stk)	Alloys	Alloys	Ila	8, 1st indent
253	01000349	S.W 1125 - 01050031 (1Stk)	Alloys	Alloys	Ila	8, 1st indent
254	01000350	S.G 1030 - 010822 (1Stk)	Alloys	Alloys	Ila	8, 1st indent
255	01000351	S.G 1120 - 01050030 (1Stk)	Alloys	Alloys	Ila	8, 1st indent
256	01000352	S.G 700 - 010875 (1Stk)	Alloys	Alloys	Ila	8, 1st indent
257	01000353	S.G 1055 - 010888 (1Stk)	Alloys	Alloys	Ila	8, 1st indent
258	01000354	S.G 920 - 010974 (1Stk)	Alloys	Alloys	Ila	8, 1st indent
259	01000355	S.G 880 - 010878 (1Stk)	Alloys	Alloys	Ila	8, 1st indent
260	01000356	S.G 1155 - 010826 (1Stk)	Alloys	Alloys	Ila	8, 1st indent
261	01000358	LW N° 2 - 01050043 (1Stk)	Alloys	Alloys	Ila	8, 1st indent
262	01000359	LW N° 3 - 01050040 (1Stk)	Alloys	Alloys	Ila	8, 1st indent
263	01000360	LW N° 4 - 01050042 (1Stk)	Alloys	Alloys	Ila	8, 1st indent
264	01000361	LW N° 5 - 01050041 (1Stk)	Alloys	Alloys	Ila	8, 1st indent
265	01000362	LW N° 6 - 01050038 (1Stk)	Alloys	Alloys	Ila	8, 1st indent
266	01000363	LW N° 1 - 01050039 (1Stk)	Alloys	Alloys	Ila	8, 1st indent
267	01000364	LW N° 7 - 01050044 (1Stk)	Alloys	Alloys	Ila	8, 1st indent
268	01000365	Elasticor ø 1.15 mm - 010267 (1Stk)	Alloys	Alloys	Ila	8, 1st indent

First Name / Name	Function	Date	Signature
Markus Blümli	Product Manager	23.6.2021	
Matthias Walther	Director of Development	23.06.2021	
Remi Meier	Product Safety Officer	23.06.2021	

Change Control:

Version	Date	Description of the Change	Reason of the Change
Version 1	12.06.2020	Basis ist die "Device Master List". Produkte die im SAP Status Desinvestiert haben wurden von der Liste entfernt. Alloys Produktliste erstmals im Excel-format.	Im Rahmen des NB Wechsels auf mdc werden die Produktlisten überprüft.
Version 2	02.11.2020/dym	Adding of the new alloys references	MD5-2960 Integration LEG-Verpackung ins SAP
Version 3	23.06.2021/dym	Deletion of the desinvested articles	DV5-2735 Desinvestition KE-LEG 2019 Some articles, already desinvested, were yet in the list.

Valid for the project and/or the product(s): Product Group "Dental Casting Alloys" (DCA)

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

N o	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	☒

N o	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	☐

List of laws, standards and norms
for the system of medical devices

3. Standards and norms for testing medical devices

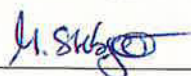
No	Code	No	Title	Issue date	Valid
1	ASTM	D 638	Standard Test Method for Tensile Properties of Plastics	2014	☐
2	ASTM	D 790-17	Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials	2017	☐
3	ASTM	B 265-15	Standard Specification for Titanium 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: 21.01.2019

Visum: 

Remi Meier
Head of Quality Management

Datum: 21.01.2019.

Visum: 

4. Änderungskontrolle

Ist eine Schulung erforderlich, hat der Prozesseigner die betroffenen Personen zu Schulung. 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.

**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



Dylan Moretti
Regulatory Affairs Manager *
Cendres+Métaux SA



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.*