

EN

EU Declaration of Conformity

We, the company Cendres+Métaux SA, Rue de Boujean 122, CH-2501 Biel/Bienne, hereby declare under sole responsibility that the following products

Dental Alloys

according to the attached list

Product list Family: Dental Alloys, Revision 01

are in conformity with the following normative documents:

Regulation (EU) 2017/745 (MDR) and, where applicable, other relevant Union legislation providing for the issuing of an EU declaration of conformity.

Common specifications applied:

N.A.

Classification according to Annex VIII, MDR (EU) 2017/745,

Basic UDI-DI according to Annex VI Part C MDR (EU) 2017/745,

And **Intended Purpose** according to the attached list:

Product list Family: Dental Alloys, Revision 01

Conformity assessment procedure: MDR (EU) 2017/745 Annex IX

Notified Body:

mdc medical device certification GmbH, Kriegerstraße 6, 70191 Stuttgart / Germany (CE 0483)

Validity: 22.02.2027

This declaration of conformity is authenticated with the following signatures:

Biel/Bienne, 29.05.2024



Dylan Moretti
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Cendres+Métaux SA



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

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CHRN-MF-20000343
SRN: CH-MF-000030696

Release

Task	Name	Function	Date	Signature
Author	Dylan Moretti	Regulatory Affairs Manager	07.03.2023	
Review	Markus Blümli	Senior Product Manager	07.03.2023	

Identification

Document No.: LDP-Dental Alloys Revision: 01

Please save document under the following name: LDP-Dental Alloys_V01

Purpose

This template defines the content of Section 1.1 of the Technical Documentation for Medical Devices based on MDR (EU) 2017/745 and RL 00001387 "Maintenance of technical documentation for dental medical devices".

1.1.2.1 List of products

Listing of the medical devices that are covered by the technical documentation. The following information are in the list:

- Catalog number
- Product name
- Device group
- Family
- Functional family
- Class MDR
- Rule MDR
- GMDN code
- Basic UDI-DI
- UDI

Catalog number	Product name	Quantity*	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
01000278	Pagalin 2	10 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081596
01000279	Pagalin 2	25 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081602
01000280	Protor 3	10 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081619
01000281	Protor 3	25 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081626
01000282	Protor 3	10.0 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081633
01000283	Protor 3	30.0 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081640
01000284	Protor 3	31.1 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081657
01000285	Neocast 3	10 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081664
01000286	Neocast 3	25 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081671
01000287	Neocast 3	10.0 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081688
01000288	Neocast 3	30.0 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081695
01000289	Neocast 3	31.1 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081701
01000290	Yellow Special	10 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081718
01000291	Yellow Special	25 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081725
01000292	Yellow Special	31.1 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081732

Catalog number	Product name	Quantity*	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
01000293	Pontor MPF	10 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081749
01000294	Pontor MPF	25 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081756
01000295	Pontor MPF	10.0 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081763
01000296	Pontor MPF	30.0 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081770
01000297	Pontor MPF	31.1 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081787
01000298	Medior 3	10 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081794
01000299	Medior 3	25 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081800
01000300	Medior 3	10.0 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081817
01000301	Medior 3	30.0 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081824
01000302	Dentalor 60	10 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081831
01000303	Dentalor 60	25 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081848
01000304	Dentalor 60	10.0 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081855
01000305	Dentalor 60	30.0 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081862
01000306	Pallorag 33	10 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081879
01000307	Pallorag 33	25 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081886

Catalog number	Product name	Quantity*	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
01000308	Solaro 3	10 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081893
01000309	Solaro 3	25 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081909
01000310	Solaro 3	10.0 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081916
01000311	Solaro 3	30.0 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081923
01000312	Solaro 3	31.1 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081930
01000313	Strator 3	10 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081947
01000314	Strator 3	25 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081954
01000315	Strator 3	10.0 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081961
01000316	Strator 3	30.0 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081978
01000317	Aurofluid 2 PF	10 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081985
01000318	Aurofluid 2 PF	25 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173081992
01000319	Aurofluid 2 PF	10.0 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173082005
01000320	Aurofluid 2 PF	30.0 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173082012
01000321	Aurofluid 2 PF	31.1 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173082029
01000322	Solaro 4	10 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173082036

Catalog number	Product name	Quantity*	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
01000323	Solaro 4	25 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173082043
01000324	Solaro 4	10.0 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173082050
01000325	Opticast	10 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173082067
01000326	Opticast	25 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173082074
01000327	Opticast	10.0 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173082081
01000328	Opticast	30.0 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173082098
01000329	Opticast	31.1 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173082104
01000338	Solaro Special	10.0 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173082197
01000339	Aurofluid 3	10.0 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173082203
01000340	Aurofluid 3	30.0 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173082210
01000341	Pallorag 35	10.0 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173082227
01000342	Pallorag 35	30.0 g	Dental Alloys	Dental Alloys	Casting Alloys	Ila	8, 1st indent	35858	764016651000041DV	97640173082234
01000170	Ceradelta 2	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080490
01000171	Ceradelta 2	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080506
01000172	Ceradelta 2	10.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080513

Catalog number	Product name	Quantity*	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
01000173	Ceradelta 2	30.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080520
01000174	Ceradelta 2	31.1 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080537
01000175	Esteticor® CC	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080544
01000176	Esteticor® CC	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080551
01000177	Esteticor® CC	10.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080568
01000178	Esteticor® CC	30.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080575
01000179	Esteticor® Plus	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080605
01000180	Esteticor® Plus	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080612
01000181	Esteticor® Plus	10.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080629
01000182	Esteticor® Plus	30.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080636
01000183	Esteticor® Plus	31.1 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080643
01000184	Esteticor® N2	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080650
01000185	Esteticor® N2	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080667
01000186	Esteticor® N2	10.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080674
01000187	Esteticor® N2	30.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080681

Catalog number	Product name	Quantity*	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
01000188	Cerapall 6	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080698
01000189	Cerapall 6	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080704
01000190	Cerapall 6	31.1 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080711
01000191	Esteticor® Implant 32	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080728
01000192	Esteticor® Implant 32	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080735
01000193	Esteticor® Implant 32	10.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080742
01000194	Esteticor® Implant 32	30.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080759
01000195	V-Delta Special	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080766
01000196	V-Delta Special	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080773
01000197	V-Delta Special	10.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080780
01000198	V-Delta Special	30.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080797
01000199	V-Delta Special	31.1 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080803
01000200	V-Delta alloy	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080810
01000201	V-Delta alloy	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080827
01000202	V-Delta alloy	31.1 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080834

Catalog number	Product name	Quantity*	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
01000203	V-Delta SF	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080841
01000204	V-Delta SF	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080858
01000205	V-Delta SF	31.1 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080865
01000206	Esteticor® NewStart	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080872
01000207	Esteticor® NewStart	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080889
01000208	Esteticor® Blancor	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080896
01000209	Esteticor® Blancor	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080902
01000210	Esteticor® Blancor	10.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080919
01000211	Esteticor® Blancor	30.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080926
01000212	Esteticor® Blancor	31.1 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080933
01000213	Cerapall 2	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080940
01000214	Cerapall 2	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080957
01000215	Cerapall 2	10.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080964
01000216	Cerapall 2	31.1 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173080971
01000220	V-Classic	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081015

Catalog number	Product name	Quantity*	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
01000221	V-Classic	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081022
01000222	V-Classic	10.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081039
01000223	V-Gnathos Plus	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081046
01000224	V-Gnathos Plus	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081053
01000225	V-Gnathos Plus	10.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081060
01000226	V-Gnathos Plus	30.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081077
01000227	V-Gnathos Plus	31.1 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081084
01000228	Esteticor® Implant 58	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081091
01000229	Esteticor® Implant 58	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081107
01000230	Esteticor® Implant 58	10.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081114
01000231	Esteticor® Implant 58	30.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081121
01000232	Esteticor® Implant 58	31.1 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081138
01000235	Esteticor® Cosmor H	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081169
01000236	Esteticor® Cosmor H	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081176
01000237	Esteticor® Cosmor H	10.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081183

Catalog number	Product name	Quantity*	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
01000238	Esteticor® Cosmor H	30.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081190
01000239	Esteticor® Economic	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081206
01000240	Esteticor® Economic	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081213
01000241	Esteticor® Economic	10.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081220
01000242	Esteticor® Economic	30.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081237
01000243	Ceradelta	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081244
01000244	Ceradelta	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081251
01000245	Ceradelta	31.1 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081268
01000246	Esteticor® Avenir	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081275
01000247	Esteticor® Avenir	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081282
01000248	Esteticor® Avenir	10.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081299
01000249	Esteticor® Avenir	30.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081305
01000250	Esteticor® Actual	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081312
01000251	Esteticor® Actual	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081329
01000252	Esteticor® Actual	10.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081336

Catalog number	Product name	Quantity*	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
01000253	Esteticor® Actual	30.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081343
01000259	Esteticor® Implant 76	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081404
01000260	Esteticor® Implant 76	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081411
01000261	Esteticor® Implant 76	10.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081428
01000262	Esteticor® Implant 76	30.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081435
01000263	Esteticor® Ecologic	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081442
01000264	Esteticor® Ecologic	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081459
01000265	Esteticor® Ideal H	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081466
01000266	Esteticor® Ideal H	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081473
01000267	Esteticor® Ideal H	10.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081480
01000268	Esteticor® Ideal H	30.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081497
01000269	BioEthic	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081503
01000270	BioEthic	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081510
01000271	BioEthic	10.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081527
01000272	BioEthic	30.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081534

Catalog number	Product name	Quantity*	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
01000273	Esteticor® Accurate 40	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081541
01000274	Esteticor® Accurate 40	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081558
01000275	Esteticor® Accurate 40	31.1 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081565
01000276	DGVO8 H	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081572
01000277	DGVO8 H	25 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173081589
01000334	V-Supragold	10.0 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173082159
01000335	Eco Delta	10 g	Dental Alloys	Dental Alloys	Ceramic Alloys	Ila	8, 1st indent	35858	764016651000040DT	97640173082166
01000358	LW N° 2	1 pc	Dental Alloys	Dental Alloys	Laser wires	Ila	8, 1st indent	38780	764016651000043DZ	97640173082395
01000359	LW N° 3	1 pc	Dental Alloys	Dental Alloys	Laser wires	Ila	8, 1st indent	38780	764016651000043DZ	97640173082401
01000360	LW N° 4	1 pc	Dental Alloys	Dental Alloys	Laser wires	Ila	8, 1st indent	38780	764016651000043DZ	97640173082418
01000361	LW N° 5	1 pc	Dental Alloys	Dental Alloys	Laser wires	Ila	8, 1st indent	38780	764016651000043DZ	97640173082425
01000362	LW N° 6	1 pc	Dental Alloys	Dental Alloys	Laser wires	Ila	8, 1st indent	38780	764016651000043DZ	97640173082432
01000363	LW N° 1	1 pc	Dental Alloys	Dental Alloys	Laser wires	Ila	8, 1st indent	38780	764016651000043DZ	97640173082449
01000364	LW N° 7	1 pc	Dental Alloys	Dental Alloys	Laser wires	Ila	8, 1st indent	38780	764016651000043DZ	97640173082456
01000345	S.G 750	1 pc	Dental Alloys	Dental Alloys	Solders	Ila	8, 1st indent	38779	764016651000042DX	97640173082265

Catalog number	Product name	Quantity*	Device group	Family	Functional family	Class MDR	Rule MDR	GMDN code	Basic UDI-DI	UDI
01000346	S.W 1100	1 pc	Dental Alloys	Dental Alloys	Solders	Ila	8, 1st indent	38779	764016651000042DX	97640173082272
01000347	S.G 1080	1 pc	Dental Alloys	Dental Alloys	Solders	Ila	8, 1st indent	38779	764016651000042DX	97640173082289
01000348	S.G 810	1 pc	Dental Alloys	Dental Alloys	Solders	Ila	8, 1st indent	38779	764016651000042DX	97640173082296
01000349	S.W 1125	1 pc	Dental Alloys	Dental Alloys	Solders	Ila	8, 1st indent	38779	764016651000042DX	97640173082302
01000350	S.G 1030	1 pc	Dental Alloys	Dental Alloys	Solders	Ila	8, 1st indent	38779	764016651000042DX	97640173082319
01000351	S.G 1120	1 pc	Dental Alloys	Dental Alloys	Solders	Ila	8, 1st indent	38779	764016651000042DX	97640173082326
01000352	S.G 700	1 pc	Dental Alloys	Dental Alloys	Solders	Ila	8, 1st indent	38779	764016651000042DX	97640173082333
01000353	S.G 1055	1 pc	Dental Alloys	Dental Alloys	Solders	Ila	8, 1st indent	38779	764016651000042DX	97640173082340
01000354	S.G 920	1 pc	Dental Alloys	Dental Alloys	Solders	Ila	8, 1st indent	38779	764016651000042DX	97640173082357
01000355	S.G 880	1 pc	Dental Alloys	Dental Alloys	Solders	Ila	8, 1st indent	38779	764016651000042DX	97640173082364
01000365	Elasticor ø 1.15 mm	1 pc	Dental Alloys	Dental Alloys	Wires	Ila	5, 3rd indent	38779	764016651000044E3	97640173082463

* For functional families Solders, Laser wires and Wires, the quantity in the product list is stated as "1 piece" since every packaging unit provides one wire with a length of 200mm. On the label, the quantity is provided in grams, because the products price is dependent on a daily rate of the precious metal alloys.

1.1.2.2 Intended purposes

Listing of the intended purposes for the functional families that are covered by the technical documentation.

Dental Alloys are semi-finished products, which are further processed by dental technicians into a custom-made device. Generally, the products are intended for use for prosthetic restorations and to support procedures in dental clinics or laboratories. The intended purpose corresponding to each functional family is defined as follows:

Functional Family	Intended purpose
Casting Alloys	The Casting Alloys, which are dental materials, are intended for use in dental prosthetic restorations for the fabrication of dental prosthesis without ceramic, such as crowns and bridges on tooth or implants predominantly for fixed dental restorations (Alloys for Inlays, Crown and Bridgework). L4: High Gold Metal Alloys for Inlays, Crown and Bridgework L5: Precious Metal Alloys for Inlays, Crown and Bridgework L6: AG-Pd-Au Alloys for Inlays, Crown and Bridgework
Ceramic Alloys	The Ceramic Alloys, which are dental materials, are intended for use in dental prosthetic restorations for the fabrication of dental prosthesis with or without ceramic, such as crowns and bridges on tooth or implants predominantly for fixed dental restorations (Alloys for the Ceramic-fused-to-metal Technique). L1: High Gold Metal Alloys for the Ceramic-fused-to-metal Technique L2: Precious Metal Alloys for the Ceramic-fused-to-metal Technique L3: Palladium-based Alloys for the Ceramic-fused-to-metal Technique L7: Universal alloys
Laser wires	The Laser wires, which are dental materials, are intended for use in dental prosthetic restorations, for joining precious metal alloys, for supplementing, for joining, and for bonding the casted or ceramic alloys restorations.
Solders	The Solders, which are dental materials, are intended for use in dental prosthetic restorations, for joining precious metal alloys, for supplementing, for joining, and for bonding the casted or ceramic alloys restorations.
Wires	The Wires, which are dental materials, are intended for use in dental prosthetic restorations for holding elements (clasps) in removable dentures.

References

- CS-Casting Alloys; Chapter A.1.1.3 of DMR Dental Alloys
- CS-Ceramic Alloys; Chapter A.1.1.3 of DMR Dental Alloys
- CS-Laser wires; Chapter A.1.1.3 of DMR Dental Alloys
- CS-Solders; Chapter A.1.1.3 of DMR Dental Alloys
- CS-Wires; Chapter A.1.1.3 of DMR Dental Alloys

Change Control

This change control lists the changes for the technical content. Changes to form FO 7.456 are documented in Appendix FO 7.456-A.

Old Version	Change date	Pos. / Section	Description of change	Reason of change	Applicant
N/A	07.03.2023	All	New creation	Establishing the technical file according to MDR	dym