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Dental alloys

Preface

This short report based on the current Medical Device Coordination Group document (MDCG 2019-9) is a summary of information regarding safety and clinical performance of the dental alloys.
This short report is a summary of information regarding safety and clinical performance of the dental alloys.

This report is not meant to be used as a practical guide for the application of our products. The current technical data for the correct handling of the products are described in the instructions for use available on www.cmsa.ch/docs, at the sales representatives or customer service of Cendres+Métaux (CM). More detailed information on products, the materials used as well as their compositions can be found in the product-specific material data sheets, the product information as well as the instructions for use. These documents as well as numerous clinical cases and scientific publications can be found on the website www.cmsa.ch/docs by entering the relevant product name.

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1 Device identification and general information

1.1 Device trade name

For individual product names of dental alloys see Chapter 1.3

1.2 Manufacturer name and address

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

1.3 Medical device description, basic UDI-DI, classification

The manufacture and distribution of dental alloys are core competencies of CM. Precious metals offer ideal properties for biocompatible, high-quality, and long-lasting dental prostheses. There is hardly a material in dentistry that offers comparable clinical evidence. Virtually everything is possible: from the fabrication of partial and full crowns to the ceramic veneering of individual crowns or wide-span fixed dental prostheses (bridges) in the posterior region or cross-arch restorations. Precious metal alloys are also suitable for removable clasp dentures (removable partial dentures) due to their mechanical properties.

Medical device	Basic UDI-DI	Class of device according to Annex VIII of the Medical Device Regulation 2017/745
High gold metal alloys for metal-ceramic restorations		
High gold content porcelain-fused-to-metal alloys (Type 4 according to ISO 22674) are characterized by their fine-grained cast structure, high corrosion resistance, biocompatibility and ease of processing. Due to the high content of Au and Pt metals, alloys from this group can be soldered without any difficulties; they are also eminently suitable for the cast-on technique when prefabricated construction elements are used for combined works.		
V-Supragold	764016651000040DT	IIa
V-Gnathos Plus	764016651000040DT	IIa
Esteticor® Ideal H	764016651000040DT	IIa
Esteticor® Avenir	764016651000040DT	IIa
Esteticor® Cosmor H	764016651000040DT	IIa
V-Classic	764016651000040DT	IIa
Esteticor® Implant 76	764016651000040DT	IIa
Precious metal alloys for metal-ceramic restorations		
Alloys with a high precious metal content (Type 4 according to ISO 22674) have a fine-grained, homogeneous cast structure, good corrosion resistance and biocompatibility when processed as specified. They are suitable for fixed dental prostheses (bridge work) with short and large spans as well as for milling and combined works, can be soldered before and after firing and are also suitable for casting onto prefabricated construction elements. Intended use: Fixed and removable dental prostheses.		
V-Deltaloy	764016651000040DT	IIa
V-Delta Special	764016651000040DT	IIa
V-Delta SF	764016651000040DT	IIa
Esteticor® Economic	764016651000040DT	IIa
Esteticor® Plus	764016651000040DT	IIa
Esteticor® Accurate 40	764016651000040DT	IIa
Esteticor® Implant 58	764016651000040DT	IIa
Palladium-based alloys for metal-ceramic restorations		
Due to the low density and high palladium or palladium silver content, these alloys (Type 4 according to ISO 22674) have a narrower processing tolerance than alloys with a high gold and precious metal content. They are suitable for bridge work with short and large spans as well as for milling and combined works and for the cast-on technique. Pd-Ag alloys can be soldered before and after firing without difficulties.		
EcoDelta	764016651000040DT	IIa
Cerapall 6	764016651000040DT	IIa
Cerapall 2	764016651000040DT	IIa
Esteticor® CC	764016651000040DT	IIa
Esteticor® Blancor	764016651000040DT	IIa
Esteticor® N2	764016651000040DT	IIa
Ceradelta 2	764016651000040DT	IIa
Esteticor® Actual	764016651000040DT	IIa
Esteticor® NewStart	764016651000040DT	IIa
Ceradelta	764016651000040DT	IIa
Esteticor® Implant 32	764016651000040DT	IIa

Medical device	Basic UDI-DI	Class of device according to Annex VIII of the Medical Device Regulation 2017/745
High gold metal alloys for dental casting		
This group casting alloys with a high gold content includes alloys with different mechanical and physical properties. This allows a wide scope of application. Type 2 alloys (high strength) are particularly suitable for inlays and bridges with short spans. Alloys of Type 4 (extra-high strength) were developed in particular for fixed dental prostheses (bridges) with large span widths, for milling work as well as for work combined with structural elements. These alloys can be soldered without any difficulties and are suitable for the cast-on technique. They are self-curing when slowly cooled to room temperature in the cylinder or soldering base. Therefore, additional thermal treatment is superfluous.		
Aurofluid 3	764016651000041DV	IIa
Opticast	764016651000041DV	IIa
Aurofluid 2 PF	764016651000041DV	IIa
Pontor MPF	764016651000041DV	IIa
Neocast 3	764016651000041DV	IIa
Protor 3	764016651000041DV	IIa
Precious metal alloys for dental casting		
Due to the lower gold and platinum content and the lower density, these casting alloys with a high precious metal content are less expensive than alloys with a high gold content. If processed as specified, these alloys have a fine-grained structure, good corrosion resistance and biocompatibility. The alloys can be soldered without difficulties and are also suitable for the cast-on technique. Most alloys in this group are self-curing when cooled to room temperature in the cylinder or in the soldering base.		
Solaro Special	764016651000041DV	IIa
Dentalor 60	764016651000041DV	IIa
Solaro 3	764016651000041DV	IIa
Medior 3	764016651000041DV	IIa
Solaro 4	764016651000041DV	IIa
Yellow Special	764016651000041DV	IIa
Ag-Pd-Au alloys for dental casting		
These casting Ag-Pd-Au alloys have a narrower processing tolerance than high gold content and reduced gold content alloys. The group includes alloys with different mechanical and physical properties. It is therefore possible to select an alloy on the basis of its composition, which is best suited to the type of work to be performed. The alloys can be soldered without difficulties and are also suitable for the cast-on technique.		
Pallorag 35	764016651000041DV	IIa
Strator 3	764016651000041DV	IIa
Pallorag 33	764016651000041DV	IIa
Pagalin 2	764016651000041DV	IIa
Alloys for dental casting and metal-ceramic restorations		
The alloys for universal use (Type 4 according to ISO 22674) can be veneered with low-melting, highly expanding ceramics as well as with resins. The alloys are Cu-free and therefore resistant to tarnishing.		
BioEthic	764016651000040DT	IIa
DGVO8 H	764016651000040DT	IIa
Esteticor® Ecologic	764016651000040DT	IIa
Solders		
When soldering, the parts to be connected are heated so much that the solder can flow into the solder joint. The solidus of the alloy must be higher than the liquidus of the solder. For porcelain-fused-to-metal alloys, there are solders before and after the ceramic bond. Pre-solders do not melt during ceramic firing. The highest firing temperature must therefore be below the solidus of the solder. Conversely, a solder used after the ceramic bond should not harm the ceramic during the ceramic firing. The liquidus of these solders should be lower than the lowest firing temperatures of ceramics.		
S.G 700	764016651000042DX	IIa
S.G 750	764016651000042DX	IIa
S.G 810	764016651000042DX	IIa
S.G 880	764016651000042DX	IIa
S.G 920	764016651000042DX	IIa
S.G 1030	764016651000042DX	IIa
S.G 1055	764016651000042DX	IIa
S.G 1080	764016651000042DX	IIa
S.G 1120	764016651000042DX	IIa
S.W 1100	764016651000042DX	IIa
S.W 1125	764016651000042DX	IIa

Medical device	Basic UDI-DI	Class of device according to Annex VIII of the Medical Device Regulation 2017/745
Wires for laser welding		
When welding the laser wire, the material is melted selectively with a laser so that it can be alloyed with the connected parts. This method is a weld in which the alloy can be easily melted.		
LW N° 1	764016651000043DZ	IIa
LW N° 2	764016651000043DZ	IIa
LW N° 3	764016651000043DZ	IIa
LW N° 4	764016651000043DZ	IIa
LW N° 5	764016651000043DZ	IIa
LW N° 6	764016651000043DZ	IIa
LW N° 7	764016651000043DZ	IIa
Wires		
The wires in precious metal alloys are used in removable dentures.		
Elasticor	764016651000044E3	IIa

1.4 Authorised representative

QualRep Services B.V.
Utrechtseweg 310 – Bldg B42
NL-6812 AR Arnhem
The Netherlands

Single registration number: NL-AR-000000537

1.5 Certificate, single registration number and notified body

Year when the first certificate was issued:	1998
Manufacturer's single registration number:	CH-MF-000030696
Notified body:	mdc medical device certification GmbH
Single identification number:	0483

PART A
Information for user and medical experts

This Section contains information regarding safety and clinical performance, especially relevant for user and medical experts.

2 Device description

2.1 Description of the device group (key functions, design characteristics, materials with body contact)

See Table in Chapter 1.3 and Chapter 2.2

2.2 Intended purpose, medical condition, anatomic locality of application

The products are intended for prosthetic restorations and to support procedures in the dental clinic or laboratory. The target groups are partially edentulous or completely edentulous patients. Concerned population is predominantly represented by adult individuals. The dental alloys are applied through the body orifice by a surgical intervention and come permanently in contact with oral tissue from the mouth (mucosal membranes, dentin).

2.3 Indications

Device name	Indications	
L1: High gold metal alloys for the ceramic-fused-to-metal technique (Type 4 according to ISO 22674)		
V-Supragold	- inlays, onlays, partial crowns (¾)	- single crowns - short-span bridgework - long-span bridgework
V-Gnathos Plus	N/A	- single crowns - short-span bridgework - long-span bridgework - milled restorations
Esteticor® Ideal H	- inlays, onlays, partial crowns (¾)	
Esteticor® Avenir	- inlays, onlays, partial crowns (¾)	
Esteticor® Cosmor H	- inlays, onlays, partial crowns (¾)	
V-Classic	N/A	
Esteticor® Implant 76	N/A	

Device name	Indications	
L2: Precious metal alloys for the ceramic-fused-to-metal technique (Type 4 according to ISO 22674)		
V-Deltaloy	N/A	- single crowns - short-span bridgework - long-span bridgework - milled restorations
V-Delta Special	N/A	
V-Delta SF	N/A	
Esteticor® Economic	N/A	
Esteticor® Plus	N/A	
Esteticor® Accurate 40	- clasps, lingual bars, palatal plates	
Esteticor® Implant 58	N/A	
L3: Palladium-based alloys for the ceramic-fused-to-metal technique (Type 4 according to ISO 22674)		
EcoDelta	- milled restorations - clasps, lingual bars, palatal plates	- single crowns - short-span bridgework - long-span bridgework
Cerapall 6	- milled restorations	
Cerapall 2	- milled restorations	
Esteticor® CC	- milled restorations - clasps, lingual bars, palatal plates	
Esteticor® Blancor	N/A	
Esteticor® N2	- milled restorations - clasps, lingual bars, palatal plates	
Ceradelta 2	- milled restorations - clasps, lingual bars, palatal plates	
Esteticor® Actual	- milled restorations	
Esteticor® NewStart	- milled restorations	
Ceradelta	- milled restorations - clasps, lingual bars, palatal plates	
Esteticor® Implant 32	- milled restorations	
L4: High gold metal alloys for inlays, crown and bridgework		
Opticast	N/A	- inlays, onlays, partial crowns (¾)
Aurofluid 2 PF	- single crowns - short-span bridgework	
Aurofluid 3	- single crowns - short-span bridgework - long-span bridgework - milled restorations - clasps, lingual bars, palatal plates	
Pontor MPF		
Neocast 3		
Protor 3		
L5: Precious metal alloys for inlays, crown and bridgework		
Solaro Special	N/A	- inlays, onlays, crowns ¾ - single crowns - short-span bridgework
Dentalor 60	- milled restorations - clasps, lingual bars, palatal plates	- inlays, onlays, crowns ¾ - single crowns - short-span bridgework - long-span bridgework
Solaro 3	- milled restorations - clasps, lingual bars, palatal plates	
Medior 3	- milled restorations - clasps, lingual bars, palatal plates	
Solaro 4	- milled restorations - clasps, lingual bars, palatal plates	
Yellow Special	N/A	
L6: Ag-Pd-Au alloys for inlays, crown and bridgework		
Strator 3	- long-span bridgework - milled restorations - clasps, lingual bars, palatal plates	- single crowns - short-span bridgework
Pallorag 33	- long-span bridgework - milled restorations	
Pallorag 35		
Pagalin 2	- inlays, onlays, partial crowns (¾)	
L7: Universal alloys		
BioEthic	N/A	- inlays, onlays, partial crowns (¾) - single crowns - short-span bridgework - long-span bridgework - milled restorations - clasps, lingual bars, palatinal plates
DGVO8 H	N/A	
Esteticor® Ecologic	N/A	

Device name	Indications
Solders	
all	Precious metal solders are used for connecting precious metal alloys
Wires for laser welding	
all	Precious metal laser wires are used for laser joining precious metal alloys
Wires	
Elasticor	Holding elements (clasps)

2.4 Contraindications

Device name	Contraindications
All dental alloys, solders, and wires	Patients who are unable to keep the regularly required check-up appointments for health reasons.
	Patients with bruxism or other para-functional habits.
	Patients with allergies to materials used in the product.
	Existing clinical picture in the patient's mouth does not permit the correct application of the products.

2.5 Affected articles

N/A

2.6 Reference and description of variants and previous generations

Variants	
N/A	N/A

Previous generations (inclusive justification of change)	
N/A	N/A

2.7 Description of any accessories

Available components	
N/A	N/A

Auxiliary parts	
N/A	N/A

Auxiliary instruments	
N/A	N/A

2.8 Combination products

The following combinations with other products are used for laser welding or soldering of CM dental alloys.

Identification / Manufacturing No.	Product name	Combination with Ceramic	Combination with laser wire	Combination with solder Before / after firing
Ceramic Alloys – L1				
01050032	V-Gnathos Plus	Creation CC	LW N°1	S.G 1030 / S.G 750
010865	Esteticor® Ideal H	Vita VMK 68	LW N°1	S.G 1030 / S.G 810; S.G 750
010972	Esteticor® Avenir	IPS d'sign	LW N°1	S.G 1030 / S.G 810; S.G 750
01050019	V-Supragold	Creation CC	LW N°2	S.G 1080 / S.G 750
010609	Esteticor® Cosmor H	Vita VMK 68	LW N°2	S.G 1030 / S.G 810; S.G 750
01050023	V-Classic	Creation CC	LW N°2	S.W 1125 / S.G 750
01000038	Esteticor® Implant® 76	IPS d'Sign	LW N°3	S.G 1055; S.G 1030 / S.G 750
Ceramic Alloys – L2				
01050001	V-Deltaloy	Creation CC	LW N°3	S.W 1100; S.G 1080 / S.G 750
01050028	V-Delta Special	Creation CC	LW N°3	S.W 1100 / S.G 750
01050017	V-Delta SF	Creation CC	LW N°3	S.W 1125; S.G 1120 / S.G 750
010617	Esteticor® Economic	Vita VMK 68	LW N°2	S.W 1100 / S.G 810; S.G 750
010620	Esteticor® Plus	Vita VMK 68	LW N°2	S.W 1100 / S.G 810; S.G 750
01000112	Esteticor® Accurate 40	Creation CC	LW N°2	S.W 1125 / S.G 750
01000030	Esteticor® Implant 58	IPS d'Sign	LW N°3	S.G 1055; S.G 1030 / S.G 750

Identification / Manufacturing No.	Product name	Combination with Ceramic	Combination with laser wire	Combination with solder Before / after firing
Ceramic Alloys – L3				
01050016	Cerapall 6	Creation CC	LW N°2	S.W 1125; S.G 1120 / S.G 750
01050011	Cerapall 2	Creation CC	LW N°2	S.W 1125; S.G 1080 / S.G 750
01050034	Eco Delta	Creation CC	LW N°3	S.G 1120 / S.G 750
01000115	Esteticor® CC	Creation CC	LW N°2	S.W 1125 / S.G 750
01000108	Esteticor® Blancor	IPS d'Sign	LW N°3	S.W 1100 / S.G 750
01000083	Esteticor® N2	Vita VMK 95	LW N°3	S.W 1100 / S.G 810; S.G 750
01050033	Ceradelta 2	Creation CC	LW N°3	S.G 1120 / S.G 750
010614	Esteticor® Actual	Vita VMK 68	LW N°3	S.W 1100 / S.G 810; S.G 750
010898	Esteticor® NewStart	Vita VMK 68	LW N°3	S.W 1100 / S.G 810; S.G 750
01050020	Ceradelta	Creation CC	LW N°2	S.G 1120 / S.G 750
01000036	Esteticor® Implant 32	IPS d'Sign	LW N°3	S.G 1055; S.G 1030 / S.G 750
Casting Alloys – L4				
010869	Opticast	N/A	LW N°5	S.G 810 / S.G 750
01050010	Aurofluid 2 PF	N/A	LW N°5	S.G 810 / S.G 750
01050021	Pontor MPF	N/A	LW N°5	S.G 810 / S.G 750
010646	Neocast 3	N/A	LW N°5	S.G 810 / S.G 750
01050009	Aurofluid 3	N/A	LW N°5	S.G 810 / S.G 750
010654	Protor 3	N/A	LW N°5	S.G 810 / S.G 750
Casting Alloys – L5				
010636	Dentalor 60	N/A	LW N°6	S.G 810 / S.G 750
01050007	Solaro 3	N/A	LW N°6	S.G 810 / S.G 750
010641	Medior 3	N/A	LW N°6	S.G 810 / S.G 750
01050008	Solaro Special	N/A	LW N°6	S.G 810 / S.G 750
01000114	Solaro 4	N/A	LW N°6	S.G 810 / S.G 750
01050026	Yellow Special	N/A	LW N°6	S.G 750 / S.G 700
Casting Alloys – L6				
010652	Pallorag 35	N/A	LW N°7	S.G 810 / S.G 750
010675	Strator 3	N/A	not weldable	S.G 810 / S.G 750
010651	Pallorag 33	N/A	LW N°7	S.G 810 / S.G 750
01050012	Pagalin 2	N/A	LW N°7	S.G 880 / S.G 750
Ceramic Alloys – L7				
010923	BioEthic	Vita 95	LW N°1	S.G 1030 / S.G 810; S.G 750
010922	DGVO8 H	Ducera Gold	LW N°4	S.G 880 / S.G 700
010994	Esteticor® Ecologic	Cosmica Evolution	LW N°4	S.G 920 / S.G 700

3 Residual risks, side effects, warnings, and preventive measures

3.1 Residual risks

- Corrosion of the denture
- Allergic reactions to materials.
- Loosening of components / of denture.
- Fracture of denture
- Aspiration of fractured fragments of denture
- Inflammation of soft tissue
- Plaque accumulation

3.2 Side effects

Device	Side effects
L1, L2, L3, L4, L5, L6, and L7 group, solders	This product must not be used in patients with allergies or suspected allergies to materials used in the product, or only after prior allergological clarification.
	Auxiliary instruments may contain nickel.
	If applied as intended, side effects can be excluded.

3.3 Warnings

Device	Warnings
L1, L2, L3, L4, L5, L6, and L7 group, solders	Magnetic resonance (MR) environment
	The device has not been evaluated for safely and compatibility in the MR environment.
	The product has not been tested for heating or migration in the MR environment.

3.4 Preventive measures

Device	Preventive measures
L1, L2, L3, L4, L5, L6, and L7 group, solders	Mixing of different alloys or alloys of similar types is not allowed!
	Wear darkened eye protection and protective gloves when melting.
	Protect eyes, hands and breathing when pickling.
	The product components are supplied non-sterile. For more information see Section “Reprocessing”.
	For your own safety, always wear suitable protective clothing. In particular when grinding, we recommend wearing protective goggles and a dust mask as well as the use of a suction unit.
Wires for laser welding	Whenever working with a laser welder, the safety precautions recommended by the manufacturer must be taken to protect the user.
	The product components are supplied non-sterile. For more information see Section “Reprocessing”.
	For your own safety, always wear suitable protective clothing. In particular when grinding, we recommend wearing protective goggles and a dust mask as well as the use of a suction unit.
Wires	The product components are supplied non-sterile. For more information see Section “Reprocessing”.
	For your own safety, always wear suitable protective clothing. In particular when grinding, we recommend wearing protective goggles and a dust mask as well as the use of a suction unit.

3.5 Other relevant aspect of safety, including a summary of any field safety corrective action

N/A

4 Summary of clinical evaluation and post-market clinical follow-up

4.1 Summary of clinical data related to equivalent device

See Chapter 4.4: Identification and justification of equivalent devices

4.2 Summary of clinical data from conducted investigations of the device before the CE-marking

N/A

4.3 Summary of clinical data from other sources

N/A

4.4 An overall summary of the safety and clinical performance

Description of the device

The manufacture and distribution of dental alloys are core competencies of CM. Precious metals offer ideal properties for biocompatible, high-quality, and long-lasting dental prostheses. There is hardly a material in dentistry that offers comparable clinical evidence. Virtually everything is possible: from the fabrication of partial and full crowns to the ceramic veneering of individual crowns or wide-span bridges in the posterior region. Precious metal alloys are also suitable for removable clasp dentures due to their mechanical properties.

Identification and justification of potential similar device(s)

As requested by the Medical Device Regulation (EU) 2017/745 (MDR) Annex XIV, clinical data from similar or equivalent devices have been evaluated. Therefore, a market search was performed in order to identify such similar devices. For this purpose, the technical, biological, and clinical properties, the intended purpose, as well as type and duration of body contact of already marketed devices were considered. ARGEDENT BIO 86 PF from the company Argen could be identified as an equivalent device to CMs dental gold alloy V-Gnathos Plus. Several other dental alloys also from the company Argen as well as from Dentsply Sirona were identified as similar devices.

One scientific article was identified by the systematic literature search in the PubMed using the similar silver-palladium based alloy Palliag M demonstrating that silver-palladium alloys are suitable substitutes for the expensive gold alloys and therefore may be a cheaper alternative. However, the work in this article dates back to the year 2002 and its knowledge is known in the meantime for two decades. There were no new additional scientific articles found by the systematic literature search regarding potential new risks relating to the dental metal alloys.

Results from medical textbooks: Current knowledge and state of the art in the medical field concerned
Considering general information on dental alloys provided in scientific textbooks it can be concluded that the main technical, clinical, and material characteristics of the dental alloys manufactured by CM represent “state of the art” technologies and materials when used as treatment materials for crowns and bridges on tooth or implants predominantly for fixed dental restorations. The textbooks identified by the search runs in the previous CER versions consistently support the long-term positive human use history of the dental alloys considered in this CER. Basically, evidence could be found for the state-of-the-art use of all these alloys:

- Ceramic alloys
- Universal alloys
- Casting alloys
- Solders
- Laser welding wire
- Further alloys
- Wires for clasps

Metallic alloys including precious alloys like gold, platinum and silver are commonly and frequently used in dentistry / in prosthodontics, amongst others due to their good corrosion resistance. However, there are reports regarding sensitization and allergies caused by metallic components used in such alloys. This does, however, not mean a basic safety issue for these alloys because allergies and incompatibilities occur relatively rare and do not cause severe and long-lasting health damage to the patient, if the concerned alloy is removed. In conclusion these drawbacks are by far outweighed by the benefits of the above-described dental alloys, which are well-known in the dental community.

Results from scientific publications in journals
The current systematic literature search in the PubMed retrieved only one article. In this article, the current status of patients with suspected dental metal allergies in Japan was assessed. As expected, most of the investigated patients had a positive response to nickel, followed by palladium and zinc, when analysed by patch testing. However, in the Instructions for Use (IFU) it is clearly stated that a suspected allergy has always to be clarified before dental treatment.

Results from post-market surveillance (PMS)
According to the complaint statistic in the previous 5 years from 2017 to 2021 a total of 0.0030% overall complaint rate was registered without serious or reportable incidences. Similarly, the complaint rate of 2022 appears also to be low with 0.0094%. This complaint statistic provides an acceptable overall complaint rate for the dental alloys.
Therefore, the identified complaint data support a positive benefits-versus-risks profile for the dental alloys demonstrating their clinically safe use and performance. Based upon the evaluation of these PMS data it can be concluded that these results support compliance of the dental alloys with the General Safety and Performance Requirements (GSPR) as especially set out in sections 1 and 8 of annex I of the MDR.
An updated complaint statistic is described in Chapter 4.5.

Results from publicly available safety databases
No safety issues could be identified for the dental alloys and its similar devices in the databases of Regulatory Authorities. The dental alloys have been safely used since their market introduction and perform as intended with no product recalls and / or adverse event reports / incidences / recalls registered in the databases of Regulatory Authorities. Based upon the evaluation of the safety data it can again be concluded that these results support compliance of the dental alloys with the GSPR especially as set out in sections 1 and 8 of annex I of the MDR.

Results from post-market clinical follow-up
Due to sufficient clinical data / evidence a post-market clinical follow-up (PMCF) was not deemed necessary before the introduction of the MDR. If Paragraph 6 of Article 61 of the MDR is fulfilled for implantable devices, such as the dental alloys are, no clinical study is required, especially if safety and clinical performance of the considered devices is based on sufficient clinical evidence. Since this particular Paragraph of the MDR is fulfilled for the dental alloys, the residual risks are acceptable and no new emerging risks are detectable, a clinical study is still not required. However, annual results from PMCF can be expected and will be collected for the PMCF report.

Accuracy of product information documents
It can be summarized that the information given in the various CM documents, the Instruction for Use (IFU), the Risk Management documents, and the product catalogue are comprehensive and conform to the clinical data and scientific information identified and evaluated in this CER.

Overall conclusion
If the evaluated clinical evidence, the scientific information, and the reported potential risks are considered, a positive overall benefit-versus-risk profile can be assumed for the dental alloys, provided that they are applied in accordance with their intended use, as outlined in the current IFUs. Based upon the clinical (experience) data and scientific information investigated in the course of this clinical evaluation, it is concluded that the dental alloys fulfill the GSPR, in particular Sections 1 and 8 according to Annex I of the MDR, saying that …

- any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.
- devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose.
- all known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use.

In conclusion, the dental alloys can be expected to exhibit the claimed safe technical and medical performance, and potential undesirable clinical effects and risks are well controlled and acceptable, when weighed against their benefits in prosthodontics.

4.5 Ongoing or planned post-market clinical follow-up

According to the post-market clinical follow-up plan the following results can be summarized for the corresponding PMCF report:
The complaint rate of 0,0041% for the report period 2024 is acceptable and comparable to the previous 5 years (2019-2023) total complaint rate of 0.0036%. Based upon the evaluation of these PMS data it can be concluded that the results support compliance of the dental alloy devices with the General Safety and Performance Requirements (GSPR) as set out in the MDR Annex I, especially sections 1 and 8. Although there were no additional clinical data identified in the literature searches or the public safety databases, it can be concluded based on these observations and the complaints data collected that the dental alloys perform as intended when used according to the Instructions for Use and are suitable for the intended dental applications.
Furthermore, the described PMCF activities for the current observation period demonstrate that:

- the dental alloys conform to the GSPR of the MDR regarding safety and clinical performance when used as intended,
- they do not show any previously unknown side-effects,
- no emerging risks are identifiable based on factual evidence for the dental alloys,
- the risk-benefit ratio referred according to Annex I of the MDR remains acceptable, and
- no systematic misuse or off-label use of the alloys is known indicating that the intended purpose is still correct.

Based on the above assessment, it can be concluded that for the dental alloys the safety and clinical performance is still valid, and a clinical trial is not required for these dental products. Updated results can be expected in the following year.

5 Possible diagnostic or therapeutic alternatives

Conventional complete dentures, partial dentures with clasps.

6 Suggested profile and training for users

The expertise of a professional dentist or dental technician is required. The current IFU must be available at all times and be completely read and understood before the first application. The fabrication of dentures and their maintenance may only be performed by qualified specialists.

7 Reference to any standards and common specifications (CS) applied

- SN EN ISO 13485: Medical devices, Quality management systems, Requirements for Regulatory purposes
- SN EN ISO 14971: Medical devices - Application of risk management to medical devices
- 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
- SN EN ISO 20417: Medical devices – Information to be supplied by the manufacturer
- SN EN ISO/IEC 17050-1: Conformity assessment - Supplier's declaration of conformity - Part 1: General requirements
- SN EN ISO/IEC 17050-2: Conformity assessment - Supplier's declaration of conformity - Part 2: Supporting documentation
- IEC 62366-1: Medical devices - Part 1: Application of usability engineering to medical devices
- SN EN 62366+A1: Medical devices - Part 1: Application of usability engineering to medical devices
- SN EN ISO 17664-1: Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices – Part 1: Critical and semi-critical medical devices
- SN EN 1641: Dentistry - Medical devices for dentistry - Materials
- ISO 22674: Dentistry - Metallic materials for fixed and removable restorations and appliances
- ISO 9693: Dentistry - Compatibility testing for metal-ceramic and ceramic-ceramic systems
- SN EN ISO 9333: Dentistry – Brazing materials
- SN EN ISO 28319: Dentistry - Laser welding and filler materials
- ISO 10271: Dentistry - Corrosion test methods for metallic materials
- SN EN ISO 6507-1: Metallic materials - Vickers hardness test - Part 1: Test method
- ISO 7405: Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
- SN EN ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- SN EN ISO 10993-3: Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- SN EN ISO 10993-5: Biological evaluation of medical devices -Part 5: Tests for in vitro cytotoxicity
- SN EN ISO 10993-10: Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- SN EN ISO 10993-12: Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- SN EN ISO 10993-18: Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process

- Common specification (CS): not yet available

PART B
Relevant information for the patient

This Section contains information regarding safety and clinical performance, especially relevant for patients.
N/A

PART C
Revision history

Edition	Issue date	Change description	Edition validated by notified body
1.0	03.2023	First edition of the SSCP	☐ Yes ☒ No Language used: english
2.0	03.2024	Second edition of the SSCP with modified Preface: MDCG document mentioned, Chapter 4.5 includes results from the ongoing PMCF.	☐ Yes ☒ No Language used: english
3.0	30.04.2025	Third edition of the SSCP with updated Chapter 4.5 "ongoing and planned PMCF" with current results from the PMCF (literature search and complaint data). This annual update is according to MDR.	☐ Yes ☐ No Language used: english

PART D
List of articles

EMDN codes:
Casting Alloys: Q010601
Ceramic Alloys: Q010601
Laser Wires: Q010601
Solders: Q010601
Wires: Q010601

Device number	Product name	Class
01000278	Pagalin 2	IIa
01000279	Pagalin 2	IIa
01000280	Protor 3	IIa
01000281	Protor 3	IIa
01000282	Protor 3	IIa
01000283	Protor 3	IIa
01000284	Protor 3	IIa
01000285	Neocast 3	IIa
01000286	Neocast 3	IIa
01000287	Neocast 3	IIa
01000288	Neocast 3	IIa
01000289	Neocast 3	IIa
01000290	Yellow Special	IIa
01000291	Yellow Special	IIa
01000292	Yellow Special	IIa
01000293	Pontor MPF	IIa
01000294	Pontor MPF	IIa
01000295	Pontor MPF	IIa
01000296	Pontor MPF	IIa
01000297	Pontor MPF	IIa
01000298	Medior 3	IIa
01000299	Medior 3	IIa
01000300	Medior 3	IIa
01000301	Medior 3	IIa
01000302	Dentalor 60	IIa
01000303	Dentalor 60	IIa
01000304	Dentalor 60	IIa
01000305	Dentalor 60	IIa

01000306	Pallorag 33	IIa
01000307	Pallorag 33	IIa
01000308	Solaro 3	IIa
01000309	Solaro 3	IIa
01000310	Solaro 3	IIa
01000311	Solaro 3	IIa
01000312	Solaro 3	IIa
01000313	Strator 3	IIa
01000314	Strator 3	IIa
01000315	Strator 3	IIa
01000316	Strator 3	IIa
01000317	Aurofluid 2 PF	IIa
01000318	Aurofluid 2 PF	IIa
01000319	Aurofluid 2 PF	IIa
01000320	Aurofluid 2 PF	IIa
01000321	Aurofluid 2 PF	IIa
01000322	Solaro 4	IIa
01000323	Solaro 4	IIa
01000324	Solaro 4	IIa
01000325	Opticast	IIa
01000326	Opticast	IIa
01000327	Opticast	IIa
01000328	Opticast	IIa
01000329	Opticast	IIa
01000338	Solaro Special	IIa
01000339	Aurofluid 3	IIa
01000340	Aurofluid 3	IIa
01000341	Pallorag 35	IIa
01000342	Pallorag 35	IIa
01000170	Ceradelta 2	IIa
01000171	Ceradelta 2	IIa
01000172	Ceradelta 2	IIa
01000173	Ceradelta 2	IIa
01000174	Ceradelta 2	IIa
01000175	Esteticor® CC	IIa
01000176	Esteticor® CC	IIa
01000177	Esteticor® CC	IIa
01000178	Esteticor® CC	IIa
01000179	Esteticor® Plus	IIa
01000180	Esteticor® Plus	IIa
01000181	Esteticor® Plus	IIa
01000182	Esteticor® Plus	IIa
01000183	Esteticor® Plus	IIa
01000184	Esteticor® N2	IIa
01000185	Esteticor® N2	IIa
01000186	Esteticor® N2	IIa
01000187	Esteticor® N2	IIa
01000188	Cerapall 6	IIa
01000189	Cerapall 6	IIa
01000190	Cerapall 6	IIa
01000191	Esteticor® Implant 32	IIa
01000192	Esteticor® Implant 32	IIa
01000193	Esteticor® Implant 32	IIa
01000194	Esteticor® Implant 32	IIa
01000195	V-Delta Special	IIa
01000196	V-Delta Special	IIa
01000197	V-Delta Special	IIa
01000198	V-Delta Special	IIa
01000199	V-Delta Special	IIa
01000200	V-Deltaloy	IIa
01000201	V-Deltaloy	IIa
01000202	V-Deltaloy	IIa
01000203	V-Delta SF	IIa
01000204	V-Delta SF	IIa
01000205	V-Delta SF	IIa

01000206	Esteticor® NewStart	IIa
01000207	Esteticor® NewStart	IIa
01000208	Esteticor® Blancor	IIa
01000209	Esteticor® Blancor	IIa
01000210	Esteticor® Blancor	IIa
01000211	Esteticor® Blancor	IIa
01000212	Esteticor® Blancor	IIa
01000213	Cerapall 2	IIa
01000214	Cerapall 2	IIa
01000215	Cerapall 2	IIa
01000216	Cerapall 2	IIa
01000220	V-Classic	IIa
01000221	V-Classic	IIa
01000222	V-Classic	IIa
01000223	V-Gnathos Plus	IIa
01000224	V-Gnathos Plus	IIa
01000225	V-Gnathos Plus	IIa
01000226	V-Gnathos Plus	IIa
01000227	V-Gnathos Plus	IIa
01000228	Esteticor® Implant 58	IIa
01000229	Esteticor® Implant 58	IIa
01000230	Esteticor® Implant 58	IIa
01000231	Esteticor® Implant 58	IIa
01000232	Esteticor® Implant 58	IIa
01000235	Esteticor® Cosmor H	IIa
01000236	Esteticor® Cosmor H	IIa
01000237	Esteticor® Cosmor H	IIa
01000238	Esteticor® Cosmor H	IIa
01000239	Esteticor® Economic	IIa
01000240	Esteticor® Economic	IIa
01000241	Esteticor® Economic	IIa
01000242	Esteticor® Economic	IIa
01000243	Ceradelta	IIa
01000244	Ceradelta	IIa
01000245	Ceradelta	IIa
01000246	Esteticor® Avenir	IIa
01000247	Esteticor® Avenir	IIa
01000248	Esteticor® Avenir	IIa
01000249	Esteticor® Avenir	IIa
01000250	Esteticor® Actual	IIa
01000251	Esteticor® Actual	IIa
01000252	Esteticor® Actual	IIa
01000253	Esteticor® Actual	IIa
01000259	Esteticor® Implant 76	IIa
01000260	Esteticor® Implant 76	IIa
01000261	Esteticor® Implant 76	IIa
01000262	Esteticor® Implant 76	IIa
01000263	Esteticor® Ecologic	IIa
01000264	Esteticor® Ecologic	IIa
01000265	Esteticor® Ideal H	IIa
01000266	Esteticor® Ideal H	IIa
01000267	Esteticor® Ideal H	IIa
01000268	Esteticor® Ideal H	IIa
01000269	BioEthic	IIa
01000270	BioEthic	IIa
01000271	BioEthic	IIa
01000272	BioEthic	IIa
01000273	Esteticor® Accurate 40	IIa
01000274	Esteticor® Accurate 40	IIa
01000275	Esteticor® Accurate 40	IIa
01000276	DGVO8 H	IIa
01000277	DGVO8 H	IIa
01000334	V-Supragold	IIa
01000335	Eco Delta	IIa

01000358	LW N° 2	IIa
01000359	LW N° 3	IIa
01000360	LW N° 4	IIa
01000361	LW N° 5	IIa
01000362	LW N° 6	IIa
01000363	LW N° 1	IIa
01000364	LW N° 7	IIa
01000345	S.G 750	IIa
01000346	S.W 1100	IIa
01000347	S.G 1080	IIa
01000348	S.G 810	IIa
01000349	S.W 1125	IIa
01000350	S.G 1030	IIa
01000351	S.G 1120	IIa
01000352	S.G 700	IIa
01000353	S.G 1055	IIa
01000354	S.G 920	IIa
01000355	S.G 880	IIa
01000365	Elasticor ø 1.15 mm	IIa

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