

prosthetic.line

Anchors

EN

Summary of Safety and Clinical Performance

English

2

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 anchors.

This short report is a summary of information regarding safety and clinical performance of the anchors.

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

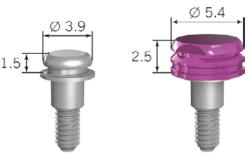
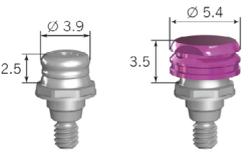
1.1 Device trade name

- CM LOC® abutment
- Dalbo® abutment
- Dalbo®-PLUS
- Dalbo®-Classic
- Dalbo®-B
- Dalbo®-Z
- CM LOC®
- Pro-Snap
- Eccentric
- Mini-Gerber PLUS

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

Medical device	Basic UDI-DI	Class of device according to Annex VIII of the Medical Device Regulation 2017/745
Anchors on implants (implant-supported)		
CM LOC® Basic Set Titanium	764016651000057EC	Ila
2x Housing Titanium (Ti6Al4V) for Pekkton® Inserts 2x Retention insert, extra-low 2x Retention insert, low 2x Retention insert, medium 2x Block-out Spacer 2x Processing insert		
		
CM LOC® abutment (Ti6Al4V)	764016651000045E5	Ilb
available with several interfaces compatible with various Straumann, Nobel Biocare, Astra Tech, Zimmer, MiS, Bio-Horizons, Camlog, Dentsply, Sweden+Martina, and Osstem implants.		
		
CM LOC® FLEX abutment (Ti6Al4V)	764016651000045E5	Ilb
available with several interfaces compatible with various Straumann, Nobel Biocare, Astra Tech, Zimmer, MiS, Bio-Horizons, Camlog, Dentsply, Sweden+Martina, and Osstem implants.		
		

Medical device	Basic UDI-DI	Class of device according to Annex VIII of the Medical Device Regulation 2017/745
CM LOC® case guide (Ti6Al4V) available with several interfaces compatible with various Straumann, Nobel Biocare, Astra Tech, Zimmer, MiS, Bio-Horizons, Camlog, Dentsply, Sweden+Martina, and Osstem implants 	764016651000056EA	IIa
CM LOC® FLEX case guide (Ti6Al4V) available with several interfaces compatible with various Straumann, Nobel Biocare, Astra Tech, Zimmer, MiS, Bio-Horizons, Camlog, Dentsply, Sweden+Martina, and Osstem implants 	764016651000056EA	IIa
CM LOC® CAD/CAM (Ti6Al4V) 	764016651000065EB	IIb
CM LOC® Housing Titanium (Ti6Al4V) for Pekkton® Inserts 	764016651000053E4	IIa
Dalbo®-PLUS Female part basic: Titanium, Elitor®  Female part elliptic: Titanium, Elitor® 	764016651000053E4	IIa
Dalbo®-Classic Female part basic: Elitor®, Valor® or Elitor®, Korak  Female part elliptic: Elitor®, Valor® or Elitor®, Korak 	764016651000053E4	IIa

Dalbo®-B	764016651000053E4	IIa
Female part: Elitor®, Elitor® or Elitor®, Korak		
		
Dalbo® abutment (Ti6Al4V)	764016651000046E7	IIb
available with several interfaces compatible with various Straumann, Nobel Biocare, Astra Tech, Zimmer, MiS, Bio-Horizons, Camlog, Dentsply, and Sweden+Martina, implants.		
		
Anchors on root canal caps (tooth-supported)		
Dalbo®-PLUS basic	Male part: 764016651000050DW	IIa
Male part: spherical ball anchor (Valor)		
Female part: lamella retention insert (Elitor®) and housing (Titanium).		
Female part: 764016651000053E4		
		
Dalbo®-PLUS elliptic	Male part: 764016651000050DW	IIa
Male part: spherical ball anchor (Valor)		
Female part: lamella retention insert (Elitor®) and housing (Titanium).		
Female part: 764016651000053E4		
		
Dalbo®-Classic basic	Male part: 764016651000050DW	IIa
Male part: spherical ball anchor (Valor)		
Female part: Elitor®		
Female part: 764016651000053E4		
		
Dalbo®-Classic elliptic	Male part: 764016651000050DW	IIa
Male part: spherical ball anchor (Valor) with reinforced retention in the denture.		
Female part: Elitor®		
Female part: 764016651000053E4		
		
Dalbo®-B	Male part: 764016651000050DW	IIa
Male part: spherical ball anchor (Elitor®)		
Female part: Elitor®		
Female part: 764016651000053E4		
		

Dalbo®-Z Male part: Elitor®. Female part: OSV	Male part: 764016651000050DW Female part: 764016651000053E4	IIa
		
CM LOC® Male part: Ceramicor® or Elitor® Female part: housing (Ti6Al4V) with Pekkton® inserts	Male part: 764016651000050DW Female part: 764016651000053E4	IIa
		
Pro-Snap Male part: spherical anchor (Ceramicor) Female part: housing (Ti6Al4V)	Male part: 764016651000050DW Female part: 764016651000053E4	IIa
		
Eccentric Male part: cylindrical anchor (OSV) with integrated solder (S.G.750) Female part: Elasticor®	Male part: 764016651000050DW Female part: 764016651000053E4	IIa
		
Mini-Gerber PLUS Male part: cylindrical anchor (Valor) Female part: Titanium	Male part: 764016651000050DW Female part: 764016651000053E4	IIa
		

A detailed list of all anchor articles with article number and classification is contained in PART D

1.4 Authorised representative and single registration number

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

Single registration number: NL-AR-000000537

1.5 Certificate, manufacturer's single registration number and notified body

Year when the first certificate was issued:	1997
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)**

An anchor is a prosthetic retaining element consisting of a female (outer) part and a male (inner) part. The male part is inserted into an implant by screwing (abutment) or soldered onto an individually fabricated root canal cap. The female part is bonded or directly polymerized into the removable denture. The root canal cap itself consists of a cast metal cap with a root canal post. Often, the prefabricated root canal post is integrated into the metal cap by cast-on. Alternatively, a metal cap can be cast directly by burning-out a root canal post.

There are fricative and retentive anchor concepts. Frictionally functioning restorations can be inserted and removed smoothly and without damaging the anchor teeth. Retentive restorations snap into place audibly and give the patient a secure feeling of a correctly fitting, removable denture.

A characteristic of the male part design is either a spherical, ball-like (Dalbo® system) or a cylindrical shape. The materials applied for the various devices are depending on their contact with the patient's body biocompatible. They typically consist of titanium, titanium alloy, or precious metal alloys. Male parts and abutments may have contact with dentin and bone-like tissue, female parts predominantly with mucosal membrane. However, the oral tissue contact is a long-term interaction due to the daily use of the prostheses.

2.2 Intended purpose, medical condition, anatomic locality of application**Implant-supported anchors**

The components are intended for use in prosthetic restorations on dental implants and to support procedures in the dental clinic or laboratory.

Tooth-supported anchors

The components are intended for use in prosthetic restorations on natural teeth and to support procedures in the dental clinic or laboratory.

or

The components are intended for use in prosthetic restorations on root canal caps and to support procedures in the dental clinic or laboratory.

Dalbo® system

The components are intended for use in prosthetic restorations on dental implants and root canal caps and to support procedures in the dental clinic or laboratory.

Functional Family	Intended purpose
Abutments	The abutments, which are part of prosthetic retaining elements, are screwed into implants and are intended for use in prosthetic restorations on dental implants to support procedures in the dental clinic or laboratory.
Case Guides	The case guides are used to determine the divergence of the implant's axes between the implants for the abutments CM LOC® and CM LOC® FLEX.
Female parts	The female parts, which are part of prosthetic retaining elements, are bonded or directly polymerized into the removable dentures and are intended for use in prosthetic restorations on dental implants or on root canal caps to support procedures in the dental clinic or laboratory.
Male parts	The male parts, which are part of prosthetic retaining elements, are soldered, laser welded, cast-on or cast directly (burn-out plastic male part) with/onto individually fabricated root canal caps and are intended for use in prosthetic restorations on root canal caps to support procedures in the dental clinic or laboratory.

2.3 Indications

Device name	Indications
CM LOC® abutment CM LOC® FLEX abutment	Implant anchorage of removable dental prostheses on implants, in combination with the specific CM LOC® system for female parts Mandible Anchorage of mandibular prosthesis on 2 or more implants Maxilla Anchorage of maxillary prosthesis on 4 or more implants
CM LOC® CAD/CAM Retention element	As an additional retention element on CAD/CAM milled dental bars, in combination with the specific CM LOC® system for female parts
CM LOC® post copings	Implant anchorage of hybrid-supported removable dental prostheses on post copings, in combination with the specific CM LOC® system for female parts Mandible Anchorage of mandibular prosthesis on 2 or more post copings Maxilla Anchorage of maxillary prosthesis on 4 or more post copings

Dalbo®-system including Dalbo® abutment, Dalbo®-PLUS, Dalbo®-Classic, and Dalbo®-B	Removable, rigidly or resiliently anchored denture on implants (Dalbo® abutment) and root canal copings
	Hybrid prosthetics
	Unilateral dentures, splinted transversally
	Partial and free-end dentures in combination
Dalbo®-Z, Pro-Snap, Eccentric, Mini-Gerber PLUS, Mini-Gerber PLUS Ring G	

2.4 Contraindications

Device name	Contraindications
CM LOC® abutment	CM LOC® abutments: Implant divergences > 20° (per implant)
CM LOC® FLEX abutment	CM LOC® FLEX abutments: Implant divergences > 30° (per implant)
	Alignment of the CM LOC® FLEX abutments outside of the mouth
	The CM LOC® abutments and CM LOC® FLEX abutments are to be used exclusively with the implant systems listed explicitly for this purpose in Table above (1.3 Medical device description)
	Use on a single implant
	Not suitable if a fixed connection is required
	Unilateral free-end prosthesis without transversal support
	Use on post copings
	Immediate restoration if immediate loading is not indicated for the implant
	Implant system is not approved for the application. Table above (1.3 Medical device description) or www.cmsa.ch/docs
	For additional contraindications, please refer to the instructions for use from the implant manufacturer
	Lacking compliance of the patient with respect to follow-up / recall instructions.
	Patients with bruxism or other para-functional habits
	In patients with a pre-existing allergy to one or more elements of the attachment element materials.
	Existing clinical picture in the patient's mouth does not permit the correct application of the products
CM LOC® post copings	Divergences > 20° (per anchoring element)
	Use on a single post coping
	Restoration of severely periodontally damaged abutment teeth
	Not suitable if a fixed connection is required
	Unilateral free-end prosthesis without transversal support
	Lacking compliance of the patient with respect to follow-up / recall instructions.
	Patients with bruxism or other para-functional habits
	In patients with a pre-existing allergy to one or more elements of the attachment element materials.
	Existing clinical picture in the patient's mouth does not permit the correct application of the products
Dalbo®-system including Dalbo® abutment, Dalbo®-PLUS, Dalbo®-Classic, and Dalbo®-B	Unilateral, partial and free-end dentures without transversal support
	Compensation of abutment divergencies outside the respective application area of the system for male part and female part
	Restoration of severely periodontally damaged teeth
	Use on implant systems which are not approved for ball anchorages
	Use for the immediate restoration of implants if the manufacturer has not approved this indication
	Lacking compliance of the patient with respect to follow-up / recall instructions.
	Patients with bruxism or other para-functional habits
	In patients with a pre-existing allergy to one or more elements of the materials used in the product.
	Existing clinical picture in the patient's mouth does not permit the correct application of the products
Dalbo®-Z, Pro-Snap, Eccentric, Mini-Gerber PLUS, Mini-Gerber PLUS Ring G	Unilateral, partial and free-end dentures without transversal support
	Restoration of severely periodontally damaged abutment teeth
	Hybrid prostheses, which are restored with a single post coping
	Lacking compliance of the patient with respect to follow-up / recall instructions.
	Patients with bruxism or other para-functional habits
	In patients with a pre-existing allergy to one or more elements of the 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
N/A	N/A
N/A	N/A

Previous generations (inclusive justification of change)		
Article No	Description of change	
055688	Elastomeric ring Dalbo®-Classic	
05001330 / 05001331	CM LOC® ENDO male part	
07000203	Adaption of case guide pin CM LOC®	
05001356	Adaption of CM LOC® Astra-Aqua Abutment	
05001352		
05001354		
05001355		
05001565		
05001352		
05001353		
05001994	CM LOC® housing titanium for Pekkton®	
055760	Dalbo®-PLUS anodized	
055750		
055752		
055771		
055886		
055889		
055890		
055891		
05000068		
05000214		
05000215		
05003013		
05001943 / 05001946		Case guide of CM LOC® FLEX Astra EV 42
Abutment Zimmer Tapered Screw-Vent CM LOC® / FLEX / Dalbo® abutment		CM LOC® male part ZimmerBiomed
055891		Single piece Dalbo® female part elliptic
05000215		
05003014		
055886		
055889		
055890		
055760	Single piece Dalbo® female part basic	
055750		
05000214		
055752		
055771		
05003503	Single piece Dalbo® female part basic (customer)	

2.7 Description of any accessories

Available components	
N/A	N/A: see 1.3 Medical device description
N/A	N/A
N/A	N/A
N/A	N/A

Auxiliary parts: CM LOC® (implant- and tooth-supported)	
07000201	Spacer 
07000202	Block-out spacer 
07000213	Impression part 

Auxiliary instruments: CM LOC®, CM LOC® FLEX, and CM LOC® CAD/CAM abutment

07000204

Analog



07000223

FLEX aligner



07000205

Multi-tool for Pekkton® retention insert



07000206

Screwdriver



07000222

FLEX screwdriver



07000217

Housing extractor

**Auxiliary instruments: Dalbo® abutment**

07000312

Abutment analogue



07000266

Abutment screwdriver

**Auxiliary parts: Dalbo®-Plus**

055760

Female part housing titanium basic



055886

Female part housing titanium elliptic



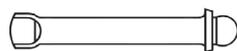
072626

Duplicating aid/spacer G



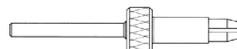
070157

Transfer jig

**Auxiliary instruments: Dalbo®-Plus**

072637

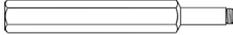
Special parallelometer insert



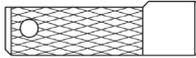
072609

Screwdriver/activator



072639 Heating rod


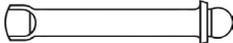
0700027 Male part gauge


0700024 Female part gauge


070222 Attachment tweezer

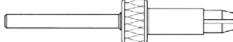

Auxiliary parts: Dalbo®-Classic

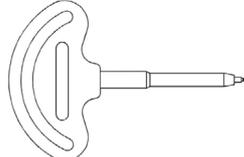
072625 Spacer G

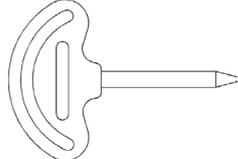

070157 Transfer jig


Auxiliary instruments: Dalbo®-Classic

070205 Instrument for mounting of elastomeric ring


072637 Special parallelometer insert


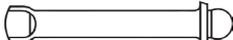
070197 Activator


070199 Deactivator


070222 Attachment tweezer


Auxiliary parts: Dalbo®-B

070440 Spacer G


070157 Transfer jig


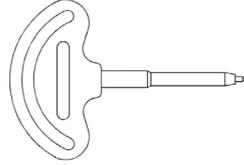
Auxiliary instruments: Dalbo®-B and Dalbo®-Z

070131 Parallelometer insert

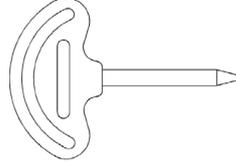

070205 Instrument for mounting of elastomeric ring



070197 Activator



070199 Deactivator



070222 Attachment tweezer

**Auxiliary parts: Dalbo®-Z**

070439 Spacer G



070157 Transfer jig

**Auxiliary instruments: CM LOC® (tooth-supported)**

07000204 Analog



07000205 Multi-tool for Pekkton® retention insert



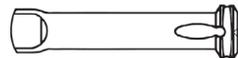
07000217 Housing extractor



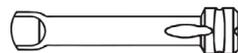
07000219 Parallelometer insert

**Auxiliary parts: Eccentric**

070161 Transfer jig



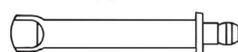
070167 Transfer jig (male part with resilience)

**Auxiliary parts: Mini-Gerber PLUS**

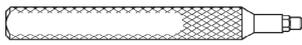
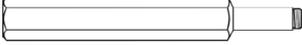
072466 Duplication aid G



072461 Transfer jig



Auxiliary instruments: Mini-Gerber PLUS

072460	Parallelometer insert	
072597	Special socket key	
072605	Heating rod	
070222	Attachment tweezer	

2.8 Combination products

The following combination products are usually used together with the various anchor parts:

- The abutment anchors are inserted by screwing into surgically placed implants (compatible implants are listed above)
 - usually 1 to 2 implants in the lower jaw (mandible)
 - usually 4 or more implants in the upper jaw (maxilla)
- The male parts of the anchors are soldered onto individually fabricated root canal caps of remaining teeth:
 - usually the root canal caps consist of a cast metal cap with root canal posts
- The female parts of the anchors are bonded or directly polymerized into the removable dentures
 - the main plastic material of the dentures is usually based on polymethylmethacrylate (PMMA)

3 Residual risks, side effects, warnings, and preventive measures**3.1 Residual risks**

For implant overdentures the complication rate may be relatively high, in the region of 30%. Similar results were also found in recent scientific articles. However, many problems are of minor significance, but repetitive. Problems reported in the literature are similar to the residual risks described in the risk documents of Cendres+Métaux SA (CM):

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

The most frequent complications related to implant overdentures reported in the literature are loss of retention or damage to the retention mechanism, fractures of the restorative material, and need of rebasing or relining. Although the complication rate may be relatively high for the removable dentures, especially in the first year, most complications are of minor significance, and the estimated survival rate of the prostheses if properly maintained may reach very high survival rates after 10 years. Therefore, a positive overall risk-benefit ratio is given in the risk management report, and it is stated that the risk of severe adverse effects due to the fracture of components of the removable dental prosthesis is very low.

Accordingly, it is concluded that

- all risks were reduced to an acceptable level,
- no unbearable accumulation of risks was identified and
- the residual risks are acceptable compared to the benefit for the patient.

3.2 Side effects

Device name	Side effects	Warnings
CM LOC® abutment CM LOC® FLEX abutment CM LOC® post coping	This product may not be used in patients with allergies to one or more elements of the product materials. In patients with suspected allergy to one or more elements of the materials, this product may only be used following allergological clarification and proof of non-existence of an allergy.	Magnetic resonance (MR) environment The device has not been evaluated for safety and compatibility in the MR environment. The product has not been tested for heating or migration in the MR environment.
Dalbo®-system including Dalbo® abutment, Dalbo®-PLUS, Dalbo®-Classic, and Dalbo®-B	Auxiliary instruments may contain nickel	Only CM LOC® system: CM CLOC® spacer The CM LOC® spacer is slightly oversized with regard to the original components. This ensures optimal spacer conditions for later polymerisation in the mouth. The spacer must not be used in place of the female part or as a temporary replacement
Dalbo®-Z, Pro-Snap, Eccentric, Mini-Gerber PLUS, Mini-Gerber PLUS Ring G	No known side effect if applied as intended	N/A

3.3 Warnings

See 3.2 Side effects

3.4 Preventive measures

Device name	Preventive measures
CM LOC® FLEX abutment	Clean and dry the abutment surface with oil-free air prior to cementation with RelyX™ Unicem or RelyX™ Unicem 2 As far as possible, align the male parts parallel to each other and to the direction of insertion. Alignment only in the mouth. Ensure that the position of the abutment is not rotated when working with the CM LOC® FLEX alignment aid Coat male part undercuts with petroleum jelly for better cleaning during cementation. (Better removal of excess composite bonding cement) It is essential to remove excess composite bonding cement
CM LOC® abutment CM LOC® FLEX abutment CM LOC® post copings	The processing, activation, deactivation, repair and periodic maintenance of the product must be carried out exclusively by trained persons The mechanical cleaning of the product using a toothbrush and toothpaste may lead to premature wear of the functional parts No cutting work may be carried out in the patient's mouth
CM LOC® abutment CM LOC® FLEX abutment	Screw in the product only once using the torque specified for this purpose In the case of immediate loading (observe implant manufacturer's indication) ensure that the tightening torque of the abutment does not exceed the torque of the implant > recommendation 5Ncm below the tightening torque of the implant
CM LOC® abutment CM LOC® FLEX abutment CM LOC® post coping	Only original tools and parts may be used The product components are supplied non-sterile Secure parts against aspiration
Dalbo®-system including Dalbo® abutment, Dalbo®-PLUS, Dalbo®-Classic, and Dalbo®-B	Before any procedure, ensure that all required product components are available in sufficient quantity 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.
Dalbo®-Z, Pro-Snap, Eccentric, Mini-Gerber PLUS, Mini-Gerber PLUS Ring G	
Dalbo®-Z, Pro-Snap, Eccentric, Mini-Gerber PLUS, Mini-Gerber PLUS Ring G	The mechanical cleaning of the product using a toothbrush and toothpaste may lead to premature wear of the functional parts

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 4.4 An overall summary of the safety and clinical performance, especially Section "Results from similar 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

An anchor is a prosthetic retaining element consisting of a female (outer) part and a male (inner) part. The male part is either soldered onto an individually fabricated root canal cap (cast post coping) or screwed into an implant (abutment anchor). The female part is bonded or directly polymerised into the removable dental prosthesis.

The post coping itself consists of a cast metal cap joint to a root canal post. As a high-quality solution, the prefabricated root canal post is integrated into the metal cap by cast-on. A more economical alternative is to use a burn-out root canal post, which is directly cast together with the metal cap. There are fricative and retentive anchor concepts. Frictionally functioning restorations can be inserted and removed smoothly and without damaging the anchor teeth. Retentive restorations snap into place audibly and give the patient a secure feeling of a correctly fitting of the removable denture.

Several types of anchors with special technical and design characteristics manufactured by Cendres+Métaux SA (CM) are available. Such anchors include the following main characteristics:

- They are ready-to-use products;
- The main components are female parts and male parts;
- Fixed on root-canal treated teeth / post copings or dental implants;
- Typical designs are ball (spherical) or cylindrical anchors;
- The kind of connection and / or retention are rigid and / or resilient;
- The retention mechanisms are friction-grip and / or retention-grip;
- The retention force of the prosthesis is adjustable with color-coded retention-inserts with varying retention force;
- The techniques or procedures to fit the male and female component parts are casting-on techniques, soldering techniques, laser-welding techniques, bonding techniques, polymerization techniques and screwing;
- Several different kinds of anchor designs are available.

The anchors manufactured by CM including all directly associated components are classified as IIb (abutments) or as class IIa medical devices (case guides, male parts and female parts) under the Medical Device Regulation (MDR). They bear the CE-mark since years / decades and are successfully internationally marketed.

Identification and justification of potential similar device(s)

A market search as requested by MEDDEV 2.7/1 rev4 was performed in order to identify potential similar or equivalent devices demonstrating substantial equivalence with the medical device under consideration (anchors). For equivalence, the technical, biological, and clinical properties, the intended purpose, as well as type and duration of body contact of the selected equivalent devices will be considered. Regarding the ability to adjust the retention force the Locator Implant Attachment manufactured by ZEST Dental Solutions (California, USA) and Novaloc by Straumann may be medical devices with similar characteristics to the CM LOC® anchor device of Cendres+Métaux SA. The technical, biological, and clinical characteristics of these two similar devices were compared with the CM LOC® system. As documented by clinical trial data of plenty of scientific articles, the locator has been successfully and safely used for the fixation of dental prostheses on two to four dental implants in partially or completely edentulous mandible or maxilla. A similar result was also obtained for the Novaloc system. The clinical trial data demonstrate that the locator or Novaloc attachment-based prosthesis is a clinical safe treatment option and is applicable for the long-term use.

Results from medical textbooks: Current knowledge and state of the art in the medical field concerned

Considering the main technical, clinical and material characteristics of the anchors manufactured by CM, and the information provided in the scientific textbooks, it can be concluded that the anchors represent “state of the art” technology and materials when used as retainers for (root-canal treated) tooth- or implant-supported dental prostheses. Anchor attachments are used to retain removable dental prostheses and indicated for all situations from an edentulous space, free-end situations or a combination of both (edentulous space and free-end denture), and for complete overdentures. Metallic alloys including titanium, stainless steel, tin, precious alloys like gold, platinum and silver are commonly and frequently used in dentistry / prosthodontics due to their good corrosion resistance. Furthermore, the thermoplastic materials used also show excellent biocompatibility. Although it is agreed in scientific textbooks that absolute biocompatibility is an utopia and that there is a potential risk of systemic toxicity, allergic reaction, local reaction (e.g. inflammation) and other reactions (e.g. genotoxicity) for all dental materials, it is concluded that the benefits of the standard dental or medical device materials are higher than any risks resulting from the particles that may dissolve from the material. The clinical concept represented by the anchor devices seems to be a reasonable and useful approach for the claimed intended use and indications. Further details are provided in the corresponding CER.

Results from scientific publications in journals

Anchor attachments in general are widely used for the fixation of removable dental prostheses supported on dental implants or abutment teeth. The results received from the clinical data with CM LOC® confirm that anchor constructions are clinically safe when used as intended for the treatment of patients with removable dental prostheses and no serious adverse effects / complications regarding the anchor prosthetic construction can be expected. Most complications need minimal maintenance.

However, based upon the appraisal of the clinical data identified by the systematic literature review in scientific journals, it can be concluded that the clinical results support compliance of the anchors with the General Safety and Performance Requirements (GSPR) as set out in annex I of the MDR and support a positive benefits-versus-risks profile for these devices. Further details are provided in the corresponding CER.

Results from post-market surveillance (PMS)

In the current report period (2021-01-01 – 2021-12-31) the complaint rate of 0.0396% is acceptable and is consistent with the low number of complaints registered in the previous 5-year report period. No serious or reportable incidence occurred in the previous and current report period. Therefore, the identified complaint data support a positive benefits-versus-risks profile for the anchors 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 anchors with the GSPR as especially set out in sections 1 and 8 of annex I of the MDR. Further details are provided in the corresponding CER. An updated complaint statistic is described in Chapter 4.5.

Results from publicly available safety databases

No safety issues could be identified for the anchors and its similar device in the databases of Regulatory Authorities. The anchors have been safely used since their 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 be concluded that these results support compliance of the anchors with the GSPR as especially set out in sections 1 and 8 of annex I of the MDR. Further details are provided in the corresponding CER.

Results from post-market clinical follow-up (PMCF)

Due to sufficient clinical data / evidence a PMCF was not deemed necessary until today. A PMCF study is still not required based on the sufficient clinical evidence and since the residual risks appear to be acceptable and not any new emerging risks are detectable. Furthermore, there were also no new relevant information relating to the safety and clinical performance for the anchors in the current PMCF report.

Accuracy of product information documents

The following documents

- Instruction for use (IFU)
- Risk management documents

were checked regarding their completeness and appropriateness in view of the scientific information and clinical data identified in the corresponding CER.

In summary all information given in the aforementioned documents are comprehensive and conform with the clinical experience data and scientific information identified in the corresponding CER.

Overall conclusion

If the evaluated clinical evidence, the scientific information and the reported potential risks are considered, a positive overall benefits-versus-risks profile can be expected for the anchors, if 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 anchors fulfill the GSPR, 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.

This conclusion is supported by the answers given to the concluding analysis questions raised prospectively in the clinical evaluation plan (CEP) and answered in the corresponding CER, respectively. Therefore, the anchors can be expected to exhibit the claimed 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 0.0144% for the current report period 2024 is acceptable and comparable to the previous 5 years (2019-2023) total complaint rate of 0.0377%. Based upon the evaluation of these PMS data it can be concluded that the results support compliance of the anchor devices with the General Safety and Performance Requirements (GSPR) as set out in the MDR Annex I, especially sections 1 and 8. There were additional clinical data identified in the literature searches for similar devices demonstrating the safety and clinical performance of anchors. Based on these observations, the search of the public safety databases, and the complaints data collected, it can be concluded that the anchors 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 anchors 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 anchors,
- the risk-benefit ratio referred according to Annex I of the MDR remains acceptable, and
- no systematic misuse or off-label use of the anchors is known indicating that the intended purpose is still correct.

Based on the above assessment, it can be concluded that for the anchors 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 20417: Medical devices - Application of risk management to medical devices
- 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: Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices
- ISO 22674: Dentistry - Metallic materials for fixed and removable restorations and appliances
- ASTM F67: Standard Specification for Unalloyed Titanium, for Surgical Implant Applications
- ISO 5832-2: Implants for surgery - Metallic materials - Part 2: Unalloyed titanium
- ASTM F136: Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications
- ASTM F899-19: Standard Specification for Wrought Stainless Steels for Surgical Instruments
- ASTM F2820: Standard Specification for Polyetherketoneketone (PEKK) Polymers for Surgical Implant Applications
- 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)
- ISO 5832-3: Implants for surgery - Metallic materials - Part 3: Wrought titanium 6-aluminium 4-vanadium alloy
- ISO 10271: Dentistry - Corrosion test methods for metallic materials
- ISO 7405: Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
- ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- 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
- ISO 10993-18: Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
- ISO 14801: Dentistry - Implants - Dynamic loading test for endosseous dental implants

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	02.2022	First edition, new version	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Language used: english
2.0	03.2023	SRN for manufacturer and authorized representative added EMDN codes listed Additional information concerning residual risks included Additional information on clinical data of equivalent devices added Results from PMCF report included	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Language used: english
3.0	03.2024	Strictly editorial modifications: BUDI for CM LOC corrected, preface mentioning the relevant MDCG document, disinvested auxiliary instruments removed, updated Chapter 4.5 with current PMCF data, adapted article list in Part D with torques	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Language used: english
4.0	30.04.2025	Strictly editorial modifications: Indications and preventive measures adapted; chapter 4.5 updated with current PMCF data	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Language used: english

PART D

List of articles

EMDN codes of anchor devices

- Abutments: P01020101
- Case Guides: P01020180
- Female parts: Q010299
- Male parts: Q010299

Device number	Product name	Class
05001296	CM LOC® Abutment Nobel Biocare Replace Select® RP 4.3 GH1 Torque 35Ncm	IIb
05001300	CM LOC® Abutment Nobel Biocare Replace Select® RP 4.3 GH2 Torque 35Ncm	IIb
05001301	CM LOC® Abutment Nobel Biocare Replace Select® RP 4.3 GH3 Torque 35Ncm	IIb
05001302	CM LOC® Abutment Nobel Biocare Replace Select® RP 4.3 GH4 Torque 35Ncm	IIb
05001303	CM LOC® Abutment Nobel Biocare Replace Select® RP 4.3 GH5 Torque 35Ncm	IIb
05001304	CM LOC® CAD/CAM Retention Element Retention Element for Bar Torque 35Ncm	IIb
05001408	CM LOC® Abutment Straumann® RN 4.8 GH1 Torque 35Ncm	IIb
05001409	CM LOC® Abutment Straumann® RN 4.8 GH2 Torque 35Ncm	IIb
05001410	CM LOC® Abutment Straumann® RN 4.8 GH3 Torque 35Ncm	IIb
05001411	CM LOC® Abutment Straumann® RN 4.8 GH4 Torque 35Ncm	IIb
05001412	CM LOC® Abutment Straumann® RN 4.8 GH5 Torque 35Ncm	IIb
05001413	CM LOC® Abutment Straumann® RC 4.1 / 4.8 GH1 Torque 35Ncm	IIb
05001414	CM LOC® Abutment Straumann® RC 4.1 / 4.8 GH2 Torque 35Ncm	IIb
05001415	CM LOC® Abutment Straumann® RC 4.1 / 4.8 GH3 Torque 35Ncm	IIb
05001416	CM LOC® Abutment Straumann® RC 4.1 / 4.8 GH4 Torque 35Ncm	IIb
05001417	CM LOC® Abutment Straumann® RC 4.1 / 4.8 GH5 Torque 35Ncm	IIb
05001418	CM LOC® Abutment Straumann® NNC 3.5 GH1 Torque 35Ncm	IIb
05001419	CM LOC® Abutment Straumann® NNC 3.5 GH2 Torque 35Ncm	IIb
05001420	CM LOC® Abutment Straumann® NNC 3.5 GH3 Torque 35Ncm	IIb
05001421	CM LOC® Abutment Straumann® NNC 3.5 GH4 Torque 35Ncm	IIb
05001422	CM LOC® Abutment Straumann® NNC 3.5 GH5 Torque 35Ncm	IIb
05001423	CM LOC® Abutment Nobel Biocare Replace Select® NP 3.5 GH1 Torque 35Ncm	IIb
05001424	CM LOC® Abutment Nobel Biocare Replace Select® NP 3.5 GH2 Torque 35Ncm	IIb
05001425	CM LOC® Abutment Nobel Biocare Replace Select® NP 3.5 GH3 Torque 35Ncm	IIb
05001426	CM LOC® Abutment Nobel Biocare Replace Select® NP 3.5 GH4 Torque 35Ncm	IIb
05001427	CM LOC® Abutment Nobel Biocare Replace Select® NP 3.5 GH5 Torque 35Ncm	IIb
05001437	CM LOC® Abutment Nobel Biocare Active® RP 4.3/5.0 GH1 Torque 35Ncm	IIb
05001438	CM LOC® Abutment Nobel Biocare Active® RP 4.3/5.0 GH2 Torque 35Ncm	IIb
05001439	CM LOC® Abutment Nobel Biocare Active® RP 4.3/5.0 GH3 Torque 35Ncm	IIb
05001440	CM LOC® Abutment Nobel Biocare Active® RP 4.3/5.0 GH4 Torque 35Ncm	IIb
05001441	CM LOC® Abutment Nobel Biocare Active® RP 4.3/5.0 GH5 Torque 35Ncm	IIb
05001452	CM LOC® Abutment Astra Tech OsseoSpeed® 3.5/4.0 GH1 Torque 25Ncm	IIb
05001453	CM LOC® Abutment Astra Tech OsseoSpeed® 3.5/4.0 GH2 Torque 25Ncm	IIb
05001454	CM LOC® Abutment Astra Tech OsseoSpeed® 3.5/4.0 GH3 Torque 25Ncm	IIb
05001455	CM LOC® Abutment Astra Tech OsseoSpeed® 3.5/4.0 GH4 Torque 25Ncm	IIb
05001456	CM LOC® Abutment Astra Tech OsseoSpeed® 3.5/4.0 GH5 Torque 25Ncm	IIb
05001457	CM LOC® Abutment Astra Tech OsseoSpeed® 4.5/5.0 GH1 Torque 25Ncm	IIb
05001458	CM LOC® Abutment Astra Tech OsseoSpeed® 4.5/5.0 GH2 Torque 25Ncm	IIb
05001459	CM LOC® Abutment Astra Tech OsseoSpeed® 4.5/5.0 GH3 Torque 25Ncm	IIb
05001460	CM LOC® Abutment Astra Tech OsseoSpeed® 4.5/5.0 GH4 Torque 25Ncm	IIb
05001461	CM LOC® Abutment Astra Tech OsseoSpeed® 4.5/5.0 GH5 Torque 25Ncm	IIb
05001462	CM LOC® Abutment Zimmer Tapered Screw-Vent® / MiS® Seven BioHorizons® Internal 3.5 GH1 Torque 30Ncm	IIb
05001463	CM LOC® Abutment Zimmer Tapered Screw-Vent® / MiS® Seven BioHorizons® Internal 3.5 GH2 Torque 30Ncm	IIb
05001464	CM LOC® Abutment Zimmer Tapered Screw-Vent® / MiS® Seven BioHorizons® Internal 3.5 GH3 Torque 30Ncm	IIb
05001465	CM LOC® Abutment Zimmer Tapered Screw-Vent® / MiS® Seven BioHorizons® Internal 3.5 GH4 Torque 30Ncm	IIb
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05001467	CM LOC® Abutment Zimmer Tapered Screw-Vent® / MiS® Seven BioHorizons® Internal 4.5 GH1 Torque 30Ncm	IIb
05001468	CM LOC® Abutment Zimmer Tapered Screw-Vent® / MiS® Seven BioHorizons® Internal 4.5 GH2 Torque 30Ncm	IIb
05001469	CM LOC® Abutment Zimmer Tapered Screw-Vent® / MiS® Seven BioHorizons® Internal 4.5 GH3 Torque 30Ncm	IIb
05001470	CM LOC® Abutment Zimmer Tapered Screw-Vent® / MiS® Seven BioHorizons® Internal 4.5 GH4 Torque 30Ncm	IIb
05001471	CM LOC® Abutment Zimmer Tapered Screw-Vent® / MiS® Seven BioHorizons® Internal 4.5 GH5 Torque 30Ncm	IIb
05001482	CM LOC® Abutment Conelog® 3.8/4.3 GH1 Torque 30Ncm	IIb
05001483	CM LOC® Abutment Conelog® 3.8/4.3 GH2 Torque 30Ncm	IIb
05001484	CM LOC® Abutment Conelog® 3.8/4.3 GH3 Torque 30Ncm	IIb

Device number	Product name	Class
05001485	CM LOC® Abutment Conelog® 3.8/4.3 GH4 Torque 30Ncm	IIb
05001486	CM LOC® Abutment Conelog® 3.8/4.3 GH5 Torque 30Ncm	IIb
05001502	CM LOC® Abutment Dyna Helix® TM/ST/DC 3.6/4.2 GH1	IIb
05001544	CM LOC® Abutment Camlog® 3.8 GH1 Torque 30Ncm	IIb
05001545	CM LOC® Abutment Camlog® 3.8 GH2 Torque 30Ncm	IIb
05001546	CM LOC® Abutment Camlog® 3.8 GH3 Torque 30Ncm	IIb
05001547	CM LOC® Abutment Camlog® 3.8 GH4 Torque 30Ncm	IIb
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05001552	CM LOC® Abutment Camlog® 4.3 GH4 Torque 30Ncm	IIb
05001963	CM LOC® Abutment Astra Tech OsseoSpeed® EV 3.6 GH1 Torque 25Ncm	IIb
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05001965	CM LOC® Abutment Astra Tech OsseoSpeed® EV 3.6 GH3 Torque 25Ncm	IIb
05001966	CM LOC® Abutment Astra Tech OsseoSpeed® EV 3.6 GH4 Torque 25Ncm	IIb
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05001968	CM LOC® Abutment Astra Tech OsseoSpeed® EV 4.2 GH1 Torque 25Ncm	IIb
05001969	CM LOC® Abutment Astra Tech OsseoSpeed® EV 4.2 GH2 Torque 25Ncm	IIb
05001970	CM LOC® Abutment Astra Tech OsseoSpeed® EV 4.2 GH3 Torque 25Ncm	IIb
05001971	CM LOC® Abutment Astra Tech OsseoSpeed® EV 4.2 GH4 Torque 25Ncm	IIb
05001972	CM LOC® Abutment Astra Tech OsseoSpeed® EV 4.2 GH5 Torque 25Ncm	IIb
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05001977	CM LOC® Abutment Astra Tech OsseoSpeed® EV 4.8 GH5 Torque 25Ncm	IIb
05002014	CM LOC® Abutment Dentsply Ankylos® C 3.5, 4.5, 5.5, 7.0 GH1 Torque 25Ncm	IIb
05002015	CM LOC® Abutment Dentsply Ankylos® C 3.5, 4.5, 5.5, 7.0 GH2 Torque 25Ncm	IIb
05002016	CM LOC® Abutment Dentsply Ankylos® C 3.5, 4.5, 5.5, 7.0 GH3 Torque 25Ncm	IIb
05002017	CM LOC® Abutment Dentsply Ankylos® C 3.5, 4.5, 5.5, 7.0 GH4 Torque 25Ncm	IIb
05002018	CM LOC® Abutment Dentsply Ankylos® C 3.5, 4.5, 5.5, 7.0 GH5 Torque 25Ncm	IIb
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05002116	CM LOC® Abutment Nobel Biocare Brånemark® RP 4.0 GH3 Torque 35Ncm	IIb
05002117	CM LOC® Abutment Nobel Biocare Brånemark® RP 4.0 GH4 Torque 35Ncm	IIb
05002118	CM LOC® Abutment Nobel Biocare Brånemark® RP 4.0 GH5 Torque 35Ncm	IIb
05002119	CM LOC® Abutment Sweden+Martina Premium Kohno 3.3 GH1 Torque 30Ncm	IIb
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05002121	CM LOC® Abutment Sweden+Martina Premium Kohno 3.3 GH3 Torque 30Ncm	IIb
05002122	CM LOC® Abutment Sweden+Martina Premium Kohno 3.3 GH4 Torque 30Ncm	IIb
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05002125	CM LOC® Abutment Sweden+Martina Premium Kohno 3.8 GH2 Torque 30Ncm	IIb
05002126	CM LOC® Abutment Sweden+Martina Premium Kohno 3.8 GH3 Torque 30Ncm	IIb
05002127	CM LOC® Abutment Sweden+Martina Premium Kohno 3.8 GH4 Torque 30Ncm	IIb
05002128	CM LOC® Abutment Sweden+Martina Premium Kohno 3.8 GH5 Torque 30Ncm	IIb
05002129	CM LOC® Abutment Sweden+Martina Premium Kohno 4.25 GH1 Torque 30Ncm	IIb
05002130	CM LOC® Abutment Sweden+Martina Premium Kohno 4.25 GH2 Torque 30Ncm	IIb
05002131	CM LOC® Abutment Sweden+Martina Premium Kohno 4.25 GH3 Torque 30Ncm	IIb
05002132	CM LOC® Abutment Sweden+Martina Premium Kohno 4.25 GH4 Torque 30Ncm	IIb
05002133	CM LOC® Abutment Sweden+Martina Premium Kohno 4.25 GH5 Torque 30Ncm	IIb
05002134	CM LOC® Abutment Sweden+Martina Premium Kohno 5.0/6.0 GH1 Torque 30Ncm	IIb
05002135	CM LOC® Abutment Sweden+Martina Premium Kohno 5.0/6.0 GH2 Torque 30Ncm	IIb
05002136	CM LOC® Abutment Sweden+Martina Premium Kohno 5.0/6.0 GH3 Torque 30Ncm	IIb
05002137	CM LOC® Abutment Sweden+Martina Premium Kohno 5.0/6.0 GH4 Torque 30Ncm	IIb
05002138	CM LOC® Abutment Sweden+Martina Premium Kohno 5.0/6.0 GH5 Torque 30Ncm	IIb
05002149	CM LOC® Abutment Osstem® SS Regular 4.8 GH1 Torque 30Ncm	IIb
05002150	CM LOC® Abutment Osstem® SS Regular 4.8 GH2 Torque 30Ncm	IIb
05002151	CM LOC® Abutment Osstem® SS Regular 4.8 GH3 Torque 30Ncm	IIb

Device number	Product name	Class
05002152	CM LOC® Abutment Osstem® SS Regular 4.8 GH4 Torque 30Ncm	IIb
05002153	CM LOC® Abutment Osstem® SS Regular 4.8 GH5 Torque 30Ncm	IIb
05002154	CM LOC® Abutment Osstem® US Regular 4.1 GH1 Torque 30Ncm	IIb
05002155	CM LOC® Abutment Osstem® US Regular 4.1 GH2 Torque 30Ncm	IIb
05002156	CM LOC® Abutment Osstem® US Regular 4.1 GH3 Torque 30Ncm	IIb
05002157	CM LOC® Abutment Osstem® US Regular 4.1 GH4 Torque 30Ncm	IIb
05002158	CM LOC® Abutment Osstem® US Regular 4.1 GH5 Torque 30Ncm	IIb
05002159	CM LOC® Abutment Osstem® T _s Regular 4.0/4.5/5.0/6.0/7.0 GH1 Torque 30Ncm	IIb
05002160	CM LOC® Abutment Osstem® T _s Regular 4.0/4.5/5.0/6.0/7.0 GH2 Torque 30Ncm	IIb
05002161	CM LOC® Abutment Osstem® T _s Regular 4.0/4.5/5.0/6.0/7.0 GH3 Torque 30Ncm	IIb
05002162	CM LOC® Abutment Osstem® T _s Regular 4.0/4.5/5.0/6.0/7.0 GH4 Torque 30Ncm	IIb
05002163	CM LOC® Abutment Osstem® T _s Regular 4.0/4.5/5.0/6.0/7.0 GH5 Torque 30Ncm	IIb
05002547	CM LOC® Abutment Straumann® NC 3.3 GH1 Torque 35Ncm	IIb
05002548	CM LOC® Abutment Straumann® NC 3.3 GH2 Torque 35Ncm	IIb
05002549	CM LOC® Abutment Straumann® NC 3.3 GH3 Torque 35Ncm	IIb
05002550	CM LOC® Abutment Straumann® NC 3.3 GH4 Torque 35Ncm	IIb
05002551	CM LOC® Abutment Straumann® NC 3.3 GH5 Torque 35Ncm	IIb
05002590	CM LOC® Abutment Osstem® T _s Mini 3.5 GH1 Torque 30Ncm	IIb
05002591	CM LOC® Abutment Osstem® T _s Mini 3.5 GH2 Torque 30Ncm	IIb
05002592	CM LOC® Abutment Osstem® T _s Mini 3.5 GH3 Torque 30Ncm	IIb
05002593	CM LOC® Abutment Osstem® T _s Mini 3.5 GH4 Torque 30Ncm	IIb
05002594	CM LOC® Abutment Osstem® T _s Mini 3.5 GH5 Torque 30Ncm	IIb
05001720	CM LOC® FLEX Abutment Straumann® RN 4.8 GH1 Torque 35Ncm	IIb
05001721	CM LOC® FLEX Abutment Straumann® RN 4.8 GH2 Torque 35Ncm	IIb
05001722	CM LOC® FLEX Abutment Straumann® RN 4.8 GH3 Torque 35Ncm	IIb
05001723	CM LOC® FLEX Abutment Straumann® RN 4.8 GH4 Torque 35Ncm	IIb
05001724	CM LOC® FLEX Abutment Straumann® RN 4.8 GH5 Torque 35Ncm	IIb
05001725	CM LOC® FLEX Abutment Straumann® RC 4.1 / 4.8 GH1 Torque 35Ncm	IIb
05001726	CM LOC® FLEX Abutment Straumann® RC 4.1 / 4.8 GH2 Torque 35Ncm	IIb
05001727	CM LOC® FLEX Abutment Straumann® RC 4.1 / 4.8 GH3 Torque 35Ncm	IIb
05001728	CM LOC® FLEX Abutment Straumann® RC 4.1 / 4.8 GH4 Torque 35Ncm	IIb
05001729	CM LOC® FLEX Abutment Straumann® RC 4.1 / 4.8 GH5 Torque 35Ncm	IIb
05001740	CM LOC® FLEX Abutment Nobel Biocare Replace Select® RP 4.3 GH1 Torque 35Ncm	IIb
05001741	CM LOC® FLEX Abutment Nobel Biocare Replace Select® RP 4.3 GH2 Torque 35Ncm	IIb
05001742	CM LOC® FLEX Abutment Nobel Biocare Replace Select® RP 4.3 GH3 Torque 35Ncm	IIb
05001743	CM LOC® FLEX Abutment Nobel Biocare Replace Select® RP 4.3 GH4 Torque 35Ncm	IIb
05001744	CM LOC® FLEX Abutment Nobel Biocare Replace Select® RP 4.3 GH5 Torque 35Ncm	IIb
05001750	CM LOC® FLEX Abutment Nobel Biocare Active® RP 4.3/5.0 GH1 Torque 35Ncm	IIb
05001751	CM LOC® FLEX Abutment Nobel Biocare Active® RP 4.3/5.0 GH2 Torque 35Ncm	IIb
05001752	CM LOC® FLEX Abutment Nobel Biocare Active® RP 4.3/5.0 GH3 Torque 35Ncm	IIb
05001753	CM LOC® FLEX Abutment Nobel Biocare Active® RP 4.3/5.0 GH4 Torque 35Ncm	IIb
05001754	CM LOC® FLEX Abutment Nobel Biocare Active® RP 4.3/5.0 GH5 Torque 35Ncm	IIb
05001770	CM LOC® FLEX Abutment Astra Tech OsseoSpeed® 4.5/5.0 GH1 Torque 25Ncm	IIb
05001771	CM LOC® FLEX Abutment Astra Tech OsseoSpeed® 4.5/5.0 GH2 Torque 25Ncm	IIb
05001772	CM LOC® FLEX Abutment Astra Tech OsseoSpeed® 4.5/5.0 GH3 Torque 25Ncm	IIb
05001773	CM LOC® FLEX Abutment Astra Tech OsseoSpeed® 4.5/5.0 GH4 Torque 25Ncm	IIb
05001774	CM LOC® FLEX Abutment Astra Tech OsseoSpeed® 4.5/5.0 GH5 Torque 25Ncm	IIb
05001780	CM LOC® FLEX Abutment Zimmer Tapered Screw-Vent® / MiS® Seven BioHorizons® Internal 4.5 GH1 Torque 30Ncm	IIb
05001781	CM LOC® FLEX Abutment Zimmer Tapered Screw-Vent® / MiS® Seven BioHorizons® Internal 4.5 GH2 Torque 30Ncm	IIb
05001782	CM LOC® FLEX Abutment Zimmer Tapered Screw-Vent® / MiS® Seven BioHorizons® Internal 4.5 GH3 Torque 30Ncm	IIb
05001783	CM LOC® FLEX Abutment Zimmer Tapered Screw-Vent® / MiS® Seven BioHorizons® Internal 4.5 GH4 Torque 30Ncm	IIb
05001784	CM LOC® FLEX Abutment Zimmer Tapered Screw-Vent® / MiS® Seven BioHorizons® Internal 4.5 GH5 Torque 30Ncm	IIb
05001790	CM LOC® FLEX Abutment Camlog® 3.8 GH1 Torque 30Ncm	IIb
05001791	CM LOC® FLEX Abutment Camlog® 3.8 GH2 Torque 30Ncm	IIb
05001792	CM LOC® FLEX Abutment Camlog® 3.8 GH3 Torque 30Ncm	IIb
05001793	CM LOC® FLEX Abutment Camlog® 3.8 GH4 Torque 30Ncm	IIb
05001795	CM LOC® FLEX Abutment Camlog® 4.3 GH1 Torque 30Ncm	IIb
05001796	CM LOC® FLEX Abutment Camlog® 4.3 GH2 Torque 30Ncm	IIb
05001797	CM LOC® FLEX Abutment Camlog® 4.3 GH3 Torque 30Ncm	IIb
05001798	CM LOC® FLEX Abutment Camlog® 4.3 GH4 Torque 30Ncm	IIb
05001805	CM LOC® FLEX Abutment Conelog® 3.8/4.3 GH1 Torque 30Ncm	IIb
05001806	CM LOC® FLEX Abutment Conelog® 3.8/4.3 GH2 Torque 30Ncm	IIb
05001807	CM LOC® FLEX Abutment Conelog® 3.8/4.3 GH3 Torque 30Ncm	IIb
05001808	CM LOC® FLEX Abutment Conelog® 3.8/4.3 GH4 Torque 30Ncm	IIb

Device number	Product name	Class
05001809	CM LOC® FLEX Abutment Conelog® 3.8/4.3 GH5 Torque 30Ncm	IIb
05001932	CM LOC® FLEX Abutment Astra Tech OsseoSpeed® EV 4.2 GH1 Torque 25Ncm	IIb
05001933	CM LOC® FLEX Abutment Astra Tech OsseoSpeed® EV 4.2 GH2 Torque 25Ncm	IIb
05001934	CM LOC® FLEX Abutment Astra Tech OsseoSpeed® EV 4.2 GH3 Torque 25Ncm	IIb
05001935	CM LOC® FLEX Abutment Astra Tech OsseoSpeed® EV 4.2 GH4 Torque 25Ncm	IIb
05001936	CM LOC® FLEX Abutment Astra Tech OsseoSpeed® EV 4.2 GH5 Torque 25Ncm	IIb
05001937	CM LOC® FLEX Abutment Astra Tech OsseoSpeed® EV 4.8 GH1 Torque 25Ncm	IIb
05001938	CM LOC® FLEX Abutment Astra Tech OsseoSpeed® EV 4.8 GH2 Torque 25Ncm	IIb
05001939	CM LOC® FLEX Abutment Astra Tech OsseoSpeed® EV 4.8 GH3 Torque 25Ncm	IIb
05001940	CM LOC® FLEX Abutment Astra Tech OsseoSpeed® EV 4.8 GH4 Torque 25Ncm	IIb
05001941	CM LOC® FLEX Abutment Astra Tech OsseoSpeed® EV 4.8 GH5 Torque 25Ncm	IIb
05002002	CM LOC® FLEX Abutment Dentsply Ankylos® C 4.5, 5.5, 7.0 GH1 Torque 25Ncm	IIb
05002003	CM LOC® FLEX Abutment Dentsply Ankylos® C 4.5, 5.5, 7.0 GH2 Torque 25Ncm	IIb
05002004	CM LOC® FLEX Abutment Dentsply Ankylos® C 4.5, 5.5, 7.0 GH3 Torque 25Ncm	IIb
05002005	CM LOC® FLEX Abutment Dentsply Ankylos® C 4.5, 5.5, 7.0 GH4 Torque 25Ncm	IIb
05002006	CM LOC® FLEX Abutment Dentsply Ankylos® C 4.5, 5.5, 7.0 GH5 Torque 25Ncm	IIb
05002261	CM LOC® FLEX Abutment Nobel Biocare Brånemark® RP 4.0 GH1 Torque 35Ncm	IIb
05002262	CM LOC® FLEX Abutment Nobel Biocare Brånemark® RP 4.0 GH2 Torque 35Ncm	IIb
05002263	CM LOC® FLEX Abutment Nobel Biocare Brånemark® RP 4.0 GH3 Torque 35Ncm	IIb
05002264	CM LOC® FLEX Abutment Nobel Biocare Brånemark® RP 4.0 GH4 Torque 35Ncm	IIb
05002265	CM LOC® FLEX Abutment Nobel Biocare Brånemark® RP 4.0 GH5 Torque 35Ncm	IIb
05002266	CM LOC® FLEX Abutment Sweden+Martina Premium Kohno 3.8 GH1 Torque 30Ncm	IIb
05002267	CM LOC® FLEX Abutment Sweden+Martina Premium Kohno 3.8 GH2 Torque 30Ncm	IIb
05002268	CM LOC® FLEX Abutment Sweden+Martina Premium Kohno 3.8 GH3 Torque 30Ncm	IIb
05002269	CM LOC® FLEX Abutment Sweden+Martina Premium Kohno 3.8 GH4 Torque 30Ncm	IIb
05002270	CM LOC® FLEX Abutment Sweden+Martina Premium Kohno 3.8 GH5 Torque 30Ncm	IIb
05002271	CM LOC® FLEX Abutment Sweden+Martina Premium Kohno 4.25 GH1 Torque 30Ncm	IIb
05002272	CM LOC® FLEX Abutment Sweden+Martina Premium Kohno 4.25 GH2 Torque 30Ncm	IIb
05002273	CM LOC® FLEX Abutment Sweden+Martina Premium Kohno 4.25 GH3 Torque 30Ncm	IIb
05002274	CM LOC® FLEX Abutment Sweden+Martina Premium Kohno 4.25 GH4 Torque 30Ncm	IIb
05002275	CM LOC® FLEX Abutment Sweden+Martina Premium Kohno 4.25 GH5 Torque 30Ncm	IIb
05002276	CM LOC® FLEX Abutment Sweden+Martina Premium Kohno 5.0/6.0 GH1 Torque 30Ncm	IIb
05002277	CM LOC® FLEX Abutment Sweden+Martina Premium Kohno 5.0/6.0 GH2 Torque 30Ncm	IIb
05002278	CM LOC® FLEX Abutment Sweden+Martina Premium Kohno 5.0/6.0 GH3 Torque 30Ncm	IIb
05002279	CM LOC® FLEX Abutment Sweden+Martina Premium Kohno 5.0/6.0 GH4 Torque 30Ncm	IIb
05002280	CM LOC® FLEX Abutment Sweden+Martina Premium Kohno 5.0/6.0 GH5 Torque 30Ncm	IIb
05002566	CM LOC® FLEX Abutment Osstem® T _s Regular 4.0/4.5/5.0/6.0/7.0 GH1 Torque 30Ncm	IIb
05002567	CM LOC® FLEX Abutment Osstem® T _s Regular 4.0/4.5/5.0/6.0/7.0 GH2 Torque 30Ncm	IIb
05002568	CM LOC® FLEX Abutment Osstem® T _s Regular 4.0/4.5/5.0/6.0/7.0 GH3 Torque 30Ncm	IIb
05002569	CM LOC® FLEX Abutment Osstem® T _s Regular 4.0/4.5/5.0/6.0/7.0 GH4 Torque 30Ncm	IIb
05002570	CM LOC® FLEX Abutment Osstem® T _s Regular 4.0/4.5/5.0/6.0/7.0 GH5 Torque 30Ncm	IIb
05002446	Dalbo® Abutment Straumann® RN 4.8, GH1 Torque 35Ncm	IIb
05002447	Dalbo® Abutment Straumann® RN 4.8, GH2 Torque 35Ncm	IIb
05002448	Dalbo® Abutment Straumann® RN 4.8, GH3 Torque 35Ncm	IIb
05002456	Dalbo® Abutment Straumann® RC 4.1/4.8, GH3 Torque 35Ncm	IIb
05002457	Dalbo® Abutment Straumann® RC 4.1/4.8, GH4 Torque 35Ncm	IIb
05002458	Dalbo® Abutment Straumann® RC 4.1/4.8, GH5 Torque 35Ncm	IIb
05002476	Dalbo® Abutment Straumann® NC 3.3, GH3 Torque 35Ncm	IIb
05002477	Dalbo® Abutment Straumann® NC 3.3, GH4 Torque 35Ncm	IIb
05002478	Dalbo® Abutment Straumann® NC 3.3, GH5 Torque 35Ncm	IIb
05002486	Dalbo® Abutment Nobel Biocare Replace Select® RP 4.3, GH1 Torque 35Ncm	IIb
05002487	Dalbo® Abutment Nobel Biocare Replace Select® RP 4.3, GH2 Torque 35Ncm	IIb
05002488	Dalbo® Abutment Nobel Biocare Replace Select® RP 4.3, GH3 Torque 35Ncm	IIb
05002496	Dalbo® Abutment Nobel Biocare Replace Select® NP 3.5, GH1 Torque 35Ncm	IIb
05002497	Dalbo® Abutment Nobel Biocare Replace Select® NP 3.5, GH2 Torque 35Ncm	IIb
05002498	Dalbo® Abutment Nobel Biocare Replace Select® NP 3.5, GH3 Torque 35Ncm	IIb
05002506	Dalbo® Abutment Nobel Biocare Active® RP 4.3/5.0, GH3 Torque 35Ncm	IIb
05002507	Dalbo® Abutment Nobel Biocare Active® RP 4.3/5.0, GH4 Torque 35Ncm	IIb
05002508	Dalbo® Abutment Nobel Biocare Active® RP 4.3/5.0, GH5 Torque 35Ncm	IIb
05002516	Dalbo® Abutment Nobel Biocare Active® NP 3.5, GH3 Torque 35Ncm	IIb
05002517	Dalbo® Abutment Nobel Biocare Active® NP 3.5, GH4 Torque 35Ncm	IIb
05002518	Dalbo® Abutment Nobel Biocare Active® NP 3.5, GH5 Torque 35Ncm	IIb
05002526	Dalbo® Abutment Nobel Biocare Brånemark® RP 4.0, GH3 Torque 35Ncm	IIb
05002527	Dalbo® Abutment Nobel Biocare Brånemark® RP 4.0, GH4 Torque 35Ncm	IIb

Device number	Product name	Class
05002528	Dalbo® Abutment Nobel Biocare Brånemark® RP 4.0, GH5 Torque 35Ncm	IIb
05002599	Dalbo® CAD/CAM Retention Element Retention Element for Bar	IIb
05002706	Dalbo® Abutment Astra Tech OsseoSpeed® EV 3.6, GH3 Torque 25Ncm	IIb
05002707	Dalbo® Abutment Astra Tech OsseoSpeed® EV 3.6, GH4 Torque 25Ncm	IIb
05002708	Dalbo® Abutment Astra Tech OsseoSpeed® EV 3.6, GH5 Torque 25Ncm	IIb
05002716	Dalbo® Abutment Astra Tech OsseoSpeed® EV 4.2, GH3 Torque 25Ncm	IIb
05002717	Dalbo® Abutment Astra Tech OsseoSpeed® EV 4.2, GH4 Torque 25Ncm	IIb
05002718	Dalbo® Abutment Astra Tech OsseoSpeed® EV 4.2, GH5 Torque 25Ncm	IIb
05002726	Dalbo® Abutment Astra Tech OsseoSpeed® EV 4.8, GH3 Torque 25Ncm	IIb
05002727	Dalbo® Abutment Astra Tech OsseoSpeed® EV 4.8, GH4 Torque 25Ncm	IIb
05002728	Dalbo® Abutment Astra Tech OsseoSpeed® EV 4.8, GH5 Torque 25Ncm	IIb
05002736	Dalbo® Abutment Astra Tech OsseoSpeed® 3.5/4.0, GH3 Torque 25Ncm	IIb
05002737	Dalbo® Abutment Astra Tech OsseoSpeed® 3.5/4.0, GH4 Torque 25Ncm	IIb
05002738	Dalbo® Abutment Astra Tech OsseoSpeed® 3.5/4.0, GH5 Torque 25Ncm	IIb
05002746	Dalbo® Abutment Astra Tech OsseoSpeed® 4.5/5.0, GH3 Torque 25Ncm	IIb
05002747	Dalbo® Abutment Astra Tech OsseoSpeed® 4.5/5.0, GH4 Torque 25Ncm	IIb
05002748	Dalbo® Abutment Astra Tech OsseoSpeed® 4.5/5.0, GH5 Torque 25Ncm	IIb
05002756	Dalbo® Abutment DENTSPLY Ankylos® C 3.5,4.5,5.5,7.0, GH3 Torque 25Ncm	IIb
05002757	Dalbo® Abutment DENTSPLY Ankylos® C 3.5,4.5,5.5,7.0, GH4 Torque 25Ncm	IIb
05002758	Dalbo® Abutment DENTSPLY Ankylos® C 3.5,4.5,5.5,7.0, GH5 Torque 25Ncm	IIb
05002766	Dalbo® Abutment Camlog® 3.8, GH1 Torque 30Ncm	IIb
05002767	Dalbo® Abutment Camlog® 3.8, GH2 Torque 30Ncm	IIb
05002768	Dalbo® Abutment Camlog® 3.8, GH3 Torque 30Ncm	IIb
05002776	Dalbo® Abutment Camlog® 4.3, GH1 Torque 30Ncm	IIb
05002777	Dalbo® Abutment Camlog® 4.3, GH2 Torque 30Ncm	IIb
05002778	Dalbo® Abutment Camlog® 4.3, GH3 Torque 30Ncm	IIb
05002786	Dalbo® Abutment Camlog® 3.8/4.3, GH3 Torque 30Ncm	IIb
05002787	Dalbo® Abutment Camlog® 3.8/4.3, GH4 Torque 30Ncm	IIb
05002788	Dalbo® Abutment Camlog® 3.8/4.3, GH5 Torque 30Ncm	IIb
05002796	Dalbo® Abutment Osstem® US Regular 4.1, GH3 Torque 30Ncm	IIb
05002797	Dalbo® Abutment Osstem® US Regular 4.1, GH4 Torque 30Ncm	IIb
05002798	Dalbo® Abutment Osstem® US Regular 4.1, GH5 Torque 30Ncm	IIb
05002906	Dalbo® Abutment Osstem® T _s Regular 4.0/4.5/5.0/6.0/7.0, GH3 Torque 30Ncm	IIb
05002907	Dalbo® Abutment Osstem® T _s Regular 4.0/4.5/5.0/6.0/7.0, GH4 Torque 30Ncm	IIb
05002908	Dalbo® Abutment Osstem® T _s Regular 4.0/4.5/5.0/6.0/7.0, GH5 Torque 30Ncm	IIb
05002916	Dalbo® Abutment Osstem® T _s Mini 3.5, GH3 Torque 30Ncm	IIb
05002917	Dalbo® Abutment Osstem® T _s Mini 3.5, GH4 Torque 30Ncm	IIb
05002918	Dalbo® Abutment Osstem® T _s Mini 3.5, GH5 Torque 30Ncm	IIb
05002926	Dalbo® Abutment Osstem® SS Regular 4.8, GH1 Torque 30Ncm	IIb
05002927	Dalbo® Abutment Osstem® SS Regular 4.8, GH2 Torque 30Ncm	IIb
05002928	Dalbo® Abutment Osstem® SS Regular 4.8, GH3 Torque 30Ncm	IIb
05002936	Dalbo® Abutment Zimmer Tapered Screw-Vent® / MiS® Seven BioHorizons® Internal 4.5, GH3 Torque 30Ncm	IIb
05002937	Dalbo® Abutment Zimmer Tapered Screw-Vent® / MiS® Seven BioHorizons® Internal 4.5, GH4 Torque 30Ncm	IIb
05002938	Dalbo® Abutment Zimmer Tapered Screw-Vent® / MiS® Seven BioHorizons® Internal 4.5, GH5 Torque 30Ncm	IIb
05002946	Dalbo® Abutment Zimmer Tapered Screw-Vent® / MiS® Seven BioHorizons® Internal 3.5, GH3 Torque 30Ncm	IIb
05002947	Dalbo® Abutment Zimmer Tapered Screw-Vent® / MiS® Seven BioHorizons® Internal 3.5, GH4 Torque 30Ncm	IIb
05002948	Dalbo® Abutment Zimmer Tapered Screw-Vent® / MiS® Seven BioHorizons® Internal 3.5, GH5 Torque 30Ncm	IIb
05002956	Dalbo® Abutment Sweden+Martina Premium Kohno 3.3, GH3 Torque 30Ncm	IIb
05002957	Dalbo® Abutment Sweden+Martina Premium Kohno 3.3, GH4 Torque 30Ncm	IIb
05002958	Dalbo® Abutment Sweden+Martina Premium Kohno 3.3, GH5 Torque 30Ncm	IIb
05002966	Dalbo® Abutment Sweden+Martina Premium Kohno 3.8, GH3 Torque 30Ncm	IIb
05002967	Dalbo® Abutment Sweden+Martina Premium Kohno 3.8, GH4 Torque 30Ncm	IIb
05002968	Dalbo® Abutment Sweden+Martina Premium Kohno 3.8, GH5 Torque 30Ncm	IIb
05002976	Dalbo® Abutment Sweden+Martina Premium Kohno 4.25, GH3 Torque 30Ncm	IIb
05002977	Dalbo® Abutment Sweden+Martina Premium Kohno 4.25, GH4 Torque 30Ncm	IIb
05002978	Dalbo® Abutment Sweden+Martina Premium Kohno 4.25, GH5 Torque 30Ncm	IIb
05002986	Dalbo® Abutment Sweden+Martina Premium Kohno 5.0/6.0, GH3 Torque 30Ncm	IIb
05002987	Dalbo® Abutment Sweden+Martina Premium Kohno 5.0/6.0, GH4 Torque 30Ncm	IIb
05002988	Dalbo® Abutment Sweden+Martina Premium Kohno 5.0/6.0, GH5 Torque 30Ncm	IIb
05001578	CM LOC® Case Guide Straumann® RN 4.8	IIa
05001579	CM LOC® Case Guide Straumann® RC 4.1 / 4.8	IIa
05001580	CM LOC® Case Guide Straumann® NNC 3.5	IIa
05001581	CM LOC® Case Guide Nobel Biocare Replace Select® NP 3.5	IIa
05001582	CM LOC® Case Guide Nobel Biocare Replace Select® RP 4.3	IIa

Device number	Product name	Class
05001584	CM LOC® Case Guide Nobel Biocare Active® RP 4.3/5.0	Ila
05001587	CM LOC® Case Guide Astra Tech OsseoSpeed® 3.5/4.0	Ila
05001588	CM LOC® Case Guide Astra Tech OsseoSpeed® 4.5/5.0	Ila
05001589	CM LOC® Case Guide Zimmer Tapered Screw-Vent® / MiS® Seven BioHorizons® Internal 3.5	Ila
05001590	CM LOC® Case Guide Zimmer Tapered Screw-Vent® / MiS® Seven BioHorizons® Internal 4.5	Ila
05001591	CM LOC® Case Guide Camlog® 3.8	Ila
05001592	CM LOC® Case Guide Camlog® 4.3	Ila
05001594	CM LOC® Case Guide Conelog® 3.8/4.3	Ila
05001981	CM LOC® Case Guide Astra Tech OsseoSpeed® EV 3.6	Ila
05001982	CM LOC® Case Guide Astra Tech OsseoSpeed® EV 4.2	Ila
05001983	CM LOC® Case Guide Astra Tech OsseoSpeed® EV 4.8	Ila
05002020	CM LOC® Case Guide Dentsply Ankylos® C 3.5, 4.5, 5.5, 7.0	Ila
05002187	CM LOC® Case Guide Nobel Biocare Active® NP 3.5	Ila
05002188	CM LOC® Case Guide Nobel Biocare Brånemark® RP 4.0	Ila
05002189	CM LOC® Case Guide Sweden+Martina Premium Kohno 3.3	Ila
05002190	CM LOC® Case Guide Sweden+Martina Premium Kohno 3.8	Ila
05002192	CM LOC® Case Guide Sweden+Martina Premium Kohno 4.25/5.0/6.0	Ila
05002195	CM LOC® Case Guide Osstem® SS Regular 4.8	Ila
05002196	CM LOC® Case Guide Osstem® US Regular 4.1	Ila
05002197	CM LOC® Case Guide Osstem® T _s Regular 4.0/4.5/5.0/6.0/7.0	Ila
05002552	CM LOC® Case Guide Straumann® NC 3.3	Ila
05002596	CM LOC® Case Guide Osstem® T _s Mini 3.5	Ila
05001884	CM LOC® FLEX Case Guide Straumann® RN 4.8	Ila
05001885	CM LOC® FLEX Case Guide Straumann® RC 4.1 / 4.8	Ila
05001888	CM LOC® FLEX Case Guide Nobel Biocare Replace Select® RP 4.3	Ila
05001890	CM LOC® FLEX Case Guide Nobel Biocare Active® RP 4.3/5.0	Ila
05001894	CM LOC® FLEX Case Guide Astra Tech OsseoSpeed® 4.5/5.0	Ila
05001896	CM LOC® FLEX Case Guide Zimmer Tapered Screw-Vent® / MiS® Seven BioHorizons® Internal 4.5	Ila
05001897	CM LOC® FLEX Case Guide Camlog® 3.8	Ila
05001898	CM LOC® FLEX Case Guide Camlog® 4.3	Ila
05001899	CM LOC® FLEX Case Guide Conelog® 3.8/4.3	Ila
05001946	CM LOC® FLEX Case Guide Astra Tech OsseoSpeed® EV 4.2	Ila
05001947	CM LOC® FLEX Case Guide Astra Tech OsseoSpeed® EV 4.8	Ila
05002008	CM LOC® FLEX Case Guide Dentsply Ankylos® C 4.5, 5.5, 7.0	Ila
05002309	CM LOC® FLEX Case Guide Nobel Biocare Brånemark® RP 4.0	Ila
05002310	CM LOC® FLEX Case Guide Sweden+Martina Premium Kohno 3.8	Ila
05002312	CM LOC® FLEX Case Guide Sweden+Martina Premium Kohno 4.25/5.0/6.0	Ila
05002586	CM LOC® FLEX Case Guide Osstem® T _s Regular 4.0/4.5/5.0/6.0/7.0	Ila
05001306	CM LOC® Housing Pekkton® for Pekkton® Inserts	Ila
05001314	CM LOC® Retention insert, extra-low	Ila
05001315	CM LOC® Retention insert, low	Ila
05001316	CM LOC® Retention insert, medium	Ila
05001317	CM LOC® Retention insert, strong	Ila
05001325	CM LOC® Basic Set Pekkton®	Ila
05001995	CM LOC® Housing Titanium for Pekkton® Inserts	Ila
05003001	CM LOC® Basic Set Titanium	Ila
05003082	CM LOC® Basic Set Titanium V1	Ila
CM031-03482	CM LOC® Basic Set Titanium	Ila
CM031-03482-01	CM LOC® Housing Titanium for Pekkton® Inserts	Ila
CM031-03483-01	CM LOC® Retention insert, extra-low	Ila
CM031-03484-01	CM LOC® Retention insert, low	Ila
CM031-03485-01	CM LOC® Retention insert, medium	Ila
CM031-08587-01	CM LOC® Retention insert, strong	Ila
051005	Dalbo®-B Elastomeric ring	Ila
051511	Dalbo®-B Female part E	Ila
055331	Dalbo®-B EK	Ila
055688	Dalbo®-Classic Elastomeric ring	Ila
055698	Dalbo®-Classic Female part E basic	Ila
055701	Dalbo®-Classic EK basic	Ila
055887	Dalbo®-Classic Female part E elliptic	Ila
055893	Dalbo®-Classic EK elliptic	Ila
055643	Dalbo®-PLUS Lamellae retention insert E	Ila
055687	Dalbo®-PLUS Tuning lamellae retention insert E	Ila
055752	Dalbo®-PLUS Female part TE basic	Ila

Device number	Product name	Class
055760	Dalbo®-PLUS Female part housing T basic	Ila
055771	Dalbo®-PLUS Tuning female part TE basic	Ila
055886	Dalbo®-PLUS Female part housing T elliptic	Ila
055890	Dalbo®-PLUS Female part TE elliptic	Ila
055891	Dalbo®-PLUS Tuning female part TE elliptic	Ila
05000068	Dalbo®-PLUS Tuning lamellae retention insert soft E	Ila
05000081	Dalbo®-PLUS Tuning lamellae retention insert forte E	Ila
05000083	Dalbo®-PLUS Tuning lamellae retention insert extra-forte E	Ila
05000214	Dalbo®-PLUS Tuning female part soft TE basic	Ila
05000215	Dalbo®-PLUS Tuning female part soft TE elliptic	Ila
05000774	Dalbo®-PLUS Lamellae retention insert E	Ila
05001240	Dalbo®-PLUS Female Part Basic	Ila
05001242	Dalbo®-PLUS lamellae retention insert E	Ila
05003503	Dalbo®-PLUS Female part TE basic (Altatec)	Ila
05003504	Dalbo®-PLUS Lamellae retention insert E (Altatec)	Ila
050273	Dalbo®-Z Elastomeric ring	Ila
051507	Dalbo®-Z Female part O	Ila
050306	Eccentric Female part EL	Ila
055507	Mini-Gerber PLUS Threaded ring T	Ila
055508	Mini-Gerber PLUS Retention insert G	Ila
055686	Mini-Gerber PLUS Female part T	Ila
055759	Mini-Gerber PLUS Ring G	Ila
05050036	Pro-Snap TK yellow	Ila
05050042	Pro-Snap Retention insert G yellow	Ila
05050043	Pro-Snap Retention insert G red	Ila
05050044	Pro-Snap Retention insert G green	Ila
05050060	Pro-Snap Housing T yellow	Ila
05050061	Pro-Snap Housing T red	Ila
05050062	Pro-Snap Housing T green	Ila
05001605	CM LOC® Male part C casting-on / soldering technique	Ila
05001606	CM LOC® Male part E laser welding technique	Ila
050423	Dalbo®-B Male part E	Ila
050427	Dalbo®-B EE	Ila
055689	Dalbo®-Classic EV basic	Ila
055892	Dalbo®-Classic EV elliptic	Ila
055921	Dalbo®-PLUS / Dalbo®-Classic / Dalbo®-B Laser male part E	Ila
055647	Dalbo®-PLUS / Dalbo® Classic Male part V	Ila
055750	Dalbo®-PLUS TEV basic	Ila
055889	Dalbo®-PLUS TEV elliptic	Ila
050272	Dalbo®-Z Male part E	Ila
050398	Dalbo®-Z OE	Ila
050345	Eccentric ELO	Ila
050397	Eccentric ELO (With resilience)	Ila
051002	Eccentric Male part O with integrated solder (S.G. 750)	Ila
051003	Eccentric Male part O (with resilience) with integrated solder (S.G. 750)	Ila
055506	Mini-Gerber PLUS Male part V	Ila
055646	Mini-Gerber PLUS TV	Ila
05050033	Pro-Snap TC yellow	Ila
05050034	Pro-Snap TC red	Ila
05050035	Pro-Snap TC green	Ila
05050037	Pro-Snap Male part C	Ila