Summary of Safety and Clinical Performance (SSCP)

In accordance with MDCG 2019-9

In accordance with the Medical Device Regulation MDR (EU) 2017/745

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Introduction

This Summary of Safety and Clinical Performance (SSCP) has been prepared in accordance with Article 32 of Regulation (EU) 2017/745 on medical devices (MDR).

The purpose of this document is to provide a summary of the key safety and clinical performance information for the Docklocs® Attachment System. The SSCP is intended for patients, users and healthcare professionals and is designed to support the safe and proper use of the product.

The SSCP does not replace the Instructions for Use (IFU), clinical judgement, or advice from qualified healthcare professionals. The information in the currently valid instructions for use is authoritative for the safe use of the product.

Brief Information for Patients:

The Docklocs® Attachment System is used to securely attach removable dentures to dental implants. The denture can be removed by the patient for cleaning and then reinserted.

What is the benefit of the system?
The system provides secure retention and stabilisation of implant-supported partial and full dentures. This can improve wearing comfort and support the function of the denture.

What are the risks?
As with all implant-supported restorations, inflammation or discomfort around the implants, or material intolerances may occur. No serious incidents were identified during the current reporting period.

How safe is the system?
During the reporting period, six complaints were documented among more than 290,000 products placed on the market. No serious incidents, vigilance reports, or field safety corrective actions were recorded.

What should I keep in mind as a patient?
The instructions of your dentist or implantologist, as well as the information on the care and aftercare of your implant restoration, should be followed. Regular check-up appointments contribute to the long-term success of the restoration.

1. Identification of the Product and the Manufacturer

The Docklocs® Attachment System for denture fixation is intended for the attachment of full dentures (overdentures) or partial dentures that are wholly or partially supported by endosseous implants in the mandible or maxilla. The Docklocs® Attachment System enables the patient to repeatedly remove and reinsert the denture.

1.1. Trade Name(s) of the Product

Trade Name	Distribution Partner/Implant Manufacturer	Item Number Identifier	Country
Docklocs			Europe
LOcON	NT-Trading GmbH & Co. KG		Europe
Clic'n Loc	LGD Dental	.CL	France
PrimeLOC	Dyna Dental, LASAK Ltd.	.P	Europe
K-Lock	Klockner, Soadco, Archimedes		Spain
Overlock	ANCLADÉN, SL	.OL	Spain
Direktlocs	Dental Direkt		Europe

Products are distinguished by adding an abbreviation to the existing item number, or by adding an additional product number from the distribution partner, which appears as a REF number on the label.

1.2. Name and Address of the Manufacturer

MEDEALIS GmbH
Im Steinboehl 9
69518 Abtsteinach
Germany

www.medealis.de
Email: office@medealis.de
Phone: +49(0)6207 2032 597

Person responsible: Klaus Krueger

1.3. Manufacturer's SRN

DE-MF-000019555

1.4. Basic UDI-DI

Basic UDI-DIs have been assigned to the products of the Docklocs® Attachment System. These are listed under 3.1 System Components.

1.5. Description

The secondary components of the Docklocs® Attachment System are classified as implantable products.

Docklocs Secondary Components
Docklocs secondary components are prefabricated dental abutments that are used in combination with endosseous implants as the basis for anchoring dentures in the maxilla or mandible. They are available in various designs and gingival heights.

1.5.1 Medical Device Nomenclature

EMDN	UMDNS	GMDN	MDN
P01020101	17-113	44879	1103

This SSCP applies to the implantable Class IIb Docklocs® secondary components (abutments). The description of additional system components is provided solely to facilitate understanding of the overall system.

1.6. Risk Class of the Medical Device

Class IIb, Rule 8

1.7. Year of the First CE Certificate of the Product

The first CE certificate for the product was issued by mdc medical device certification GmbH on 30 July 2018.

1.8. Authorised Representative; Name and SRN

No authorised representative has been designated.

1.9. Name of the Notified Body

mdc medical device certification GmbH
Kriegerstraße 6 / 70191 Stuttgart

Identification number: 0483

2. Intended Purpose of the Device

2.1. Intended Purpose

The Docklocs® Attachment System is intended for the retention of removable full or partial dentures supported by endosseous dental implants in the maxilla or mandible. The system enables the retention of removable implant-supported partial or full dentures, as well as their repeated removal and reinsertion by the patient.

The system is intended to be used exclusively by appropriately qualified dental professionals.

2.2 Indication(s) and Target Group(s)

INDICATIONS

- The Docklocs secondary components are intended for connection with endosseous dental implants in the maxilla or mandible.
- The Docklocs® cap is intended for the retention of removable dentures on individually manufactured implant-supported bar constructions.
- The matrix system attaches the denture to the secondary components via a detachable snap-fit connection.
- The screwdrivers are intended for tightening or loosening the secondary components and retaining screws.
- The auxiliary instruments and accessories are intended for the planning and fabrication of the prosthetic restoration.

INTENDED USERS AND PATIENT GROUP

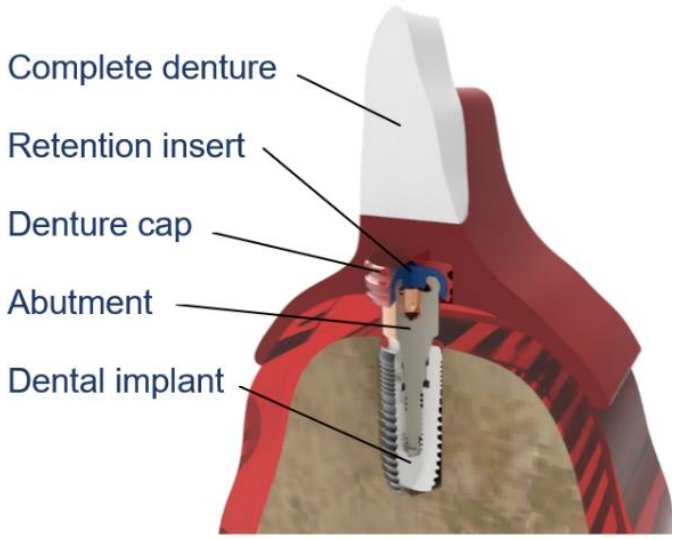
- The Attachment System is to be used exclusively by dental professionals!
- The Attachment System is intended for patients undergoing treatment with dental implants.

2.3 Contraindications and/or Limitations

CONTRAINDICATIONS

- Use with a single implant is not recommended where the vertical divergence exceeds 20 degrees.
- Use is not recommended where the divergence between the implant axes exceeds 40 degrees.
- The Attachment System is not suitable where complete fixation of the dental prosthesis is desired.
- The Attachment System is not suitable for patients who suffer from hypersensitivity or an allergy to titanium (Ti-6Al-4V), zirconium carbonitride (ZrCN), or polyamide PA (material of the retention inserts).

3. Description of the Product



The Docklocs® Attachment System is an implant-supported retention system for attaching removable partial or full dentures to osseointegrated dental implants.
The system consists of secondary components (abutments), retention housings, and replaceable retention inserts. The abutments are connected to suitable dental implants and serve as the connecting element between the implant and the prosthetic restoration.
The retention housings are integrated into the denture. Through their defined geometry and material properties, the retention inserts generate the required

retention force between the denture and the abutment. Depending on the clinical situation, different retention levels and designs are available.
The clinical performance of the system consists of the reliable retention, stabilisation and support of removable implant-supported dentures.

3.1. Overview of System Components

3.1.1 Secondary Components (Abutments)

Docklocs secondary components are prefabricated dental abutments that, in combination with endosseous implants, are used as the basis for anchoring dentures in the maxilla or mandible. They are available in various designs and gingival heights. The secondary components are compatible with numerous implant systems.

Secondary Components			
Products	**Image**	**Material**	**Number Basic UDI-DI**
Abutment, one-piece, straight		Titanium Grade 5(1) Ti-6Al-4V in accordance with ASTM F136 and ISO 5832-3, and zirconium carbonitride (ZrCN)(2) coating	++EMESA001YM
Abutment, angled, 18° with retaining screw		Titanium Grade 5(1) Ti-6Al-4V in accordance with ASTM F136 and ISO 5832-3, and zirconium carbonitride (ZrCN)(2) coating	++EMESA002YP
Cap/Bar Abutment		Titanium alloy(1) and zirconium carbonitride(2) coating	++EMESA001YM
Retaining Screws		Titanium Grade 5(1) Ti-6Al-4V in accordance with ASTM F136 and ISO 5832-3	++EMESA004YT

Treatment Units, Secondary Components			
Products	**Image**	**Material**	**Number Basic UDI-DI**
Abutment Set A One-piece straight abutment with retention housing with processing insert, retention insert blue/pink/clear/red/orange/green, and block-out ring and parallelisation post		Titanium alloy(1) with zirconium carbonitride (ZrCN)(2) coating, polyethylene(5), polyamide(3), TPE(6)/silicone(7)	++EMESA003YR
Abutment Set B Angled 18° abutment with retaining screw, retention housing with processing insert, retention insert red/orange/green, and block-out ring and parallelisation post		Titanium alloy(1) with zirconium carbonitride (ZrCN)(2) coating, polyethylene(5), polyamide(3), TPE(6)/silicone(7)	++EMESA003YR
Docklocs Bar Abutment Set		Titanium alloy(1) with zirconium carbonitride (ZrCN)(2) coating, polyethylene(5), polyamide(3), TPE(6)/silicone(7)	++EMESA003YR

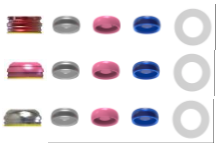
All secondary components are for single use and are supplied non-sterile.
The products come into contact with the oral mucosa and saliva.

Validated sterilisation methods:

Method	Procedure	Temperature	Minimum Holding Time	Drying Time
Steam	Vacuum Process (3x fractionated pre-vacuum)	134°C	5 minutes	20 minutes
Steam	Vacuum Process (3x fractionated pre-vacuum)	132°C	4 minutes	20 minutes

3.1.2 Matrix System

The matrix system is constructed in two parts and consists of a retention housing, which is attached to the denture, and a plastic retention insert, which transfers the retentive force to the secondary component through its geometry (detachable snap-fit connection). For the fabrication of the prosthetic restoration, the user has access to retention housings in various designs (geometry, material) as well as seven retention inserts in different colours. The colour indicates to the user the field of application and the retentive force to be achieved. A distinction is made between two fields of application, in which the angular difference between the secondary components may be up to 20° or up to 40°, and between three retentive (holding) forces: light, medium and strong.

Matrix System			
Products	**Image**	**Material**	**Number Basic UDI-DI**
Standard Laboratory Set Retention housing with processing insert, black, retention insert blue/pink/clear, and block-out ring		Titanium alloy(1), polyethylene(5), polyamide(3) (PA12), TPE(5)/silicone(6)	++EMESB004Z2
Laboratory Set for Extended Angulation Retention housing with processing insert, black, retention insert red/orange/green, and block-out ring		Titanium alloy(1), polyethylene(5), polyamide(3) (PA12), TPE(5)/silicone(6)	++EMESB004Z2
Bar Laboratory Set Retention housing with processing insert, yellow, Retention insert blue/pink/clear and block-out ring		Titanium alloy(1), polyethylene(5), polyamide(3) (PA12), TPE(5)/silicone(6)	++EMESB004Z2
Laboratory Set with Zirconia Housing		Zirconia, polyethylene(5), polyamide(3) (PA12), TPE(5)/silicone(6)	++EMESB004Z2
Retention Inserts HPP		Polyamide 12-GB30(3)	++EMESB001YU
Retention Inserts, Standard		Polyamide 6.6(4)	++EMESB001YU
Retention Housing, Titanium, with Processing Insert, Black		Titanium alloy(1) and PE(5)	++EMESB002YW
Retention Housing, Titanium, with Processing Insert, Yellow			
Retention Housing, Zirconia, with Processing Insert		Zirconia(13) and PE(5)	++EMESB003YY

All parts of the matrix system are for single use and are supplied non-sterile.
The products come into contact with saliva.

The sterilisation method:
Use only disinfectants with proven efficacy (e.g. VAH/DGHM or FDA approval, or CE marking). Always follow the information, instructions and warnings of the respective disinfectant manufacturer.

Validated procedure for the disinfection of products that cannot be sterilised.

Disinfectant: Cidex® OPA from JOHNSON & JOHNSON GMBH.
(Cidex® OPA is a registered trademark of Johnson & Johnson)

The medical device is to be fully immersed in CIDEX® OPA solution at room temperature (20°C) for at least 5 minutes. Care must be taken to ensure that all lumens are completely wetted and all air pockets are eliminated. The product is then to be removed from the solution and thoroughly decontaminated in accordance with the rinsing instructions below.

• After removal from the CIDEX® OPA solution, fully immerse the medical device in 1 litre of demineralised water. Then rinse the medical device under running water for 30 seconds.

• Repeat both steps, immersion and rinsing, once more to ensure the disinfectant is completely removed.

• After the second rinse, carry out a final rinse in 70% isopropanol for 10 seconds

3.1.3 System Tools

The system tools are designed for tightening and loosening the Docklocs secondary components and retaining screws. They have a shaft for rotary dental instruments in accordance with DIN EN ISO 1797-1. For the screwdriver with retaining sleeve, the secondary component is additionally held on the instrument via the retaining sleeve. They are machine-driven.

System Tool with Contra-Angle Connection			
Products	**Image**	**Material**	**Number Basic UDI-DI**
Screwdriver for system abutments with shaft for contra-angles		Surgical steel (12)	++EMESG00122
Screwdriver with retaining sleeve for Docklocs abutments with shaft for contra-angles		Surgical steel(12) and retaining sleeve made of PEEK(8)	++EMESG00224
Hexagon screwdriver 1.25mm for Docklocs abutments and retaining screws with shaft for contra-angles		Surgical steel (12)	++EMESG00122
Screwdriver with retaining sleeve for Docklocs Zeramex abutments with shaft for contra-angles and ZrCN coating		Surgical steel(12) (ZrCN(2) coating) and retaining sleeve made of PEEK(8)	++EMESG00326

The instruments are intended for repeated use. The products come into brief contact with the oral mucosa and saliva.

The sterilisation methods:

Method	Procedure	Temperature	Minimum Holding Time	Drying Time
Steam	Vacuum Process (3x fractionated pre-vacuum)	134°C	5 minutes	20 minutes
Steam	Vacuum Process (3x fractionated pre-vacuum)	132°C	4 minutes	20 minutes

3.1.4 Auxiliary Instruments

The universal instruments are designed for exchanging the retention inserts from the retention housing. The rose-gold attachment of the four-part universal instrument is used for manually tightening and loosening the Docklocs secondary components. The angle gauge is used to determine the angular difference of the secondary components. It is used in the oral cavity or on the model and is reusable.

Auxiliary Instruments			
Products	**Image**	**Material**	**Number Basic UDI-DI**
Universal Instrument Practice		Surgical steel (11) (12)	++EMESH00129
Universal Instrument four-part		Surgical steel(11) (12) with ZrCN(2) coating and retaining sleeve made of PEEK(8)	++EMESH00129
Angle Gauge		Surgical steel (10)	++EMESH00129

The instruments are intended for repeated use. The products come into brief contact with the oral mucosa and saliva.

The validated sterilisation methods:

Method	Procedure	Temperature	Minimum Holding Time	Drying Time
Steam	Vacuum Process (3x fractionated pre-vacuum)	134°C	5 minutes	20 minutes
Steam	Vacuum Process (3x fractionated pre-vacuum)	132°C	4 minutes	20 minutes

3.1.5 System Accessories

System accessories such as the block-out ring, laboratory analogue, spacer sleeve, impression post with impression cap, impression post with black processing insert, and selection abutments are available to the user as auxiliary parts for prosthetic reconstruction.

System Accessories			
Products	**Image**	**Material**	**Number Basic UDI-DI**
Processing Insert		Polyethylene(5)	++EMESK0012W
Spacer Sleeve		Polyoxymethylene (POM) (9)	++EMESK0012W
Impression Post		Titanium alloy(1) and polyethylene	++EMESK0022Y
Impression Post Implant with retaining screw		Titanium alloy(1)	++EMESK0022Y
Impression Cap		Polyoxymethylene (POM) (9)	++EMESK0012W
Parallelisation Post		Polyethylene(6)	++EMESK0012W

Block-Out Ring		Silicone(5)/TPE(6)	++EMESK0012W
Laboratory Analogue, Straight		Titanium alloy(1)	++EMESK0022Y
Laboratory Analogue, Angled		Titanium alloy(1)	++EMESK0022Y
Scan Cap		PEEK MT[8]	++EMESK0012W

All parts of the system accessories are for single use and are supplied non-sterile.
With the exception of the laboratory analogues, which are used only in the laboratory, the products come into brief contact with the oral mucosa and saliva.

The sterilisation method:
Docklocs retention inserts, processing inserts, block-out ring, parallelisation posts, retention housing with processing insert, and impression post with processing insert may only be sterilised chemically.
A liquid chemical sterilant approved by the FDA or another competent regulatory authority for critical products that are heat-sensitive and incompatible with sterilisation methods such as steam and low-temperature gas/steam/plasma processes may be used to sterilise the product in accordance with the manufacturer's instructions.

The following sterilisation methods apply to the impression post implant with retaining screw:

Method	Procedure	Temperature	Minimum Holding Time	Drying Time
Steam	Vacuum Process (3x fractionated pre-vacuum)	134°C	5 minutes	20 minutes
Steam	Vacuum Process (3x fractionated pre-vacuum)	132°C	4 minutes	20 minutes

3.1.6 Materials Used in the Products

Titanium alloy										
		Standards	Chemical Composition (% by weight)							
			C	AL	V	Y	Fe	O	N	H	Ti
(1)	Titanium Grade 5 Titanium Grade 23 (Titanium Alloy)	Material No.: 3.7165 EN: TiAl6V4 ELI ISO: 5832-2	max. 0.08	5.50-6.50	3.50-4.50	max. 0.005	max. 0.25	max. 0.13	max. 0.05	max. 0.012	Balance

Coating										
		Abbreviation	Chemical Composition (% by weight)							
(2)	Zirconium Carbonitride	ZrCN	Cr + Fe	O	C	N	H	Zr		
			max. 0.20	max. 0.18	max. 0.50	max. 0.025	max. 0.005	min. 99.2		

Plastics			
		Abbreviation	Remark
(3)	Polyamide 12	PA12-GB30	Polyamide 12 with 30% glass beads
(4)	Polyamide 6.6	PA6.6	Nylon
(5)	Polyethylene	PE	
(6)	Thermoplastic Elastomers	TPE	
(7)	Silicone	SI	
(8)	Polyetheretherketone	PEEK	
(9)	Polyoxymethylene	POM	

Surgical Steel										
		Standards	Chemical Composition (% by weight)							
			C	Si	Mn	P	S	Cr	Ni	N	FE
(10)	1.4301	Material No.: 1.4301 DIN EN 10088-3: X5CrNi 18-10	max. 0.03	max. 1.00	max. 2.00	max. 0.045	max. 0.03	18.0-19.5	10.0-10.5	max. 0.10	Balance

		Standards	Chemical Composition (% by weight)										
(11)	1.4305	Material No.: 1.4305 DIN EN 10088-3: X8CrNiS18-9	C	Si	Mn	P	S	Cr	Ni	Cu	Mo	N	FE
			max. 0.10	max. 1.00	max. 2.00	max. 0.045	0.15-0.35	17.0-19.0	8.00-10.00	max. 1.00	max. 0.70	max. 0.10	Ba-lance

		Standards	Chemical Composition (% by weight)							
(12)	1.4035	Material No.: 1.4035 DIN EN 10088-3: X46CrS13	C	Si	Mn	P	S	Cr	Ni	FE
			0.43-0.50	max. 1.00	max. 1.00	max. 0.04	max. 0.03	12,5-14.5	max. 1.00	Balance

Zirconia						
		Abbreviation	Chemical Composition (% by weight)			
(13)	Zirconia	ZrO_2	ZrO_2	Y2O3	Al 2O 3	$SiO_2 + Fe_2O_3 + Na_2O$
			90.0-95.0	4.0-10.0	max. 2.00	max. 0.50

3.2. Reference to Previous Generations

There are no earlier variations or versions of the system.

3.3. Accessory Parts

There are no additional accessory parts.

3.4. Products Used in Combination with the Docklocs Products.

Matching Docklocs secondary components are available for the implant systems listed in the table.

Table 1: Compatible Implant Systems

Implant System
Straumann®
Bone Level NC
Bone Level RC
Tissue Level NNC
Tissue Level RN
Tissue Level WN
BLX®
LOGON®
LOGON 3,3mm
LOGON 3,8mm
LOGON 4,3mm
LOGON 5,0mm
Camlog®
iSy®
Camlog® Ø3.3mm
Camlog® Ø3.8mm
Camlog® Ø4.3mm
Camlog® Ø5.0mm
Conelog® Ø3.3mm
Conelog® Ø3.8mm
Conelog® Ø4.3mm
Conelog® Ø5.0mm
MegaGen
AnyRidge®
AnyOne® Onestage
AnyOne® Internal
AnyOne® mini

BLUEDIAMOND® NC
BLUEDIAMOND® RC
Botticelli
Botticelli small
Botticelli regular
Bego
Sub-Tec S / RI / RS / RSX 3.75mm-4.1mm
Sub-Tec S / RI / RS / RSX 4.5mm
OSSTEM®/ HiOssen Implant®
TS System Mini (gelb)/ET-System Mini (gelb)
TS System Regular (grün)/ET-System Regular (grün)
NEODENT®
Grand Morse®
Champions
Champions (R)evolution®
Dyna Dental®
Helix
Medentis®
ICX
Dentsply Sirona®
Astra OsseoSpeed® TX Aqua 3.5mm/4mm
Astra OsseoSpeed® TX Lilac 4.5mm/5mm
Astra OsseoSpeed® Profile EV 3.6mm
Astra OsseoSpeed® Profile EV 4.2mm
Astra OsseoSpeed® Profile EV 4.8mm
Ankylos® C/X
Nobel Biocare®
NobelReplace® Tri-Channel 3.5mm
NobelReplace® Tri-Channel 4.3mm
NobelReplace® Tri-Channel 5.0mm
NobelActive® Conical NP
NobelActive® Conical RP
Brånemark System® External Hex NP
Brånemark System® External Hex RP
Brånemark System® External Hex WP
Zimmer Biomet®
Tapered Screw-Vent® 3.5mm
Tapered Screw-Vent® 4.5mm
Tapered Screw-Vent® 5.7mm
3i External Hex NP 3.25mm/3.4mm
3i External Hex RP 4,1mm
3.4mm Certain® Connection
4.1mm Certain® Connection
BioHorizons®
Tapered Internal Implant System 3.5mm
Tapered Internal Implant System 4.5mm
Tapered Internal Implant System 5.7mm
LASAK
BioniQ Regular
BioniQ Narrow
Bredent Medical
SKY®
copaSKY®
Southern Implants®
EXTERNAL HEX Ø3,0mm
EXTERNAL HEX Ø3,25mm
EXTERNAL HEX Ø4,0mm

DEEP CONICAL Ø3,0mm
DEEP CONICAL Ø3,5/4,0mm
DEEP CONICAL Ø5,0mm
Tri-NEX Ø3,5mm
Tri-NEX Ø4,3mm
Tri-NEX Ø5,0mm
SP1
Internal Hex/Provata
Internal Provata Ø3,3mm
IT **Connection** Ø4,8mm
IT **Connection** Ø6,5mm
C-Tech Implant
EL/Esthetic Line
Global D
In-Kone® ST
DEEP
DESIGN®
SWEDEN & MARTINA®
Premium Kohno® 3.3
Premium Kohno® 3.8
Prama®
Products marked with ® are registered trademarks of the respective manufacturer.

4. Risks and Warnings

4.1. Residual Risks and Undesirable Effects

As with all implant-supported restorations, treatment-related risks affecting both implantological and prosthetic aspects may also occur when using the Docklocs® Attachment System. Dental procedures may give rise to side effects such as bleeding, haematoma and infection. Further side effects may include inflammatory reactions (mucositis, peri-implantitis) in the soft tissue.
In patients with intolerances, the materials used may trigger side effects in the form of an allergic reaction, which may manifest locally as mucosal reactions, contact stomatitis, or inflammatory changes in the peri-implant soft tissue. In sensitive patients, the insertion and removal of the secondary components may trigger a gag reflex (pharyngeal reflex).

4.1.1. Quantitative Data

Key Figure	Value
Patient Treatments	ca. 12.850
Retention Insert Replacements	ca. 50.000
Complaints	6
Serious Incidents	0
Vigilance Reports	0
FSCA	0
Open CAPA	0

During the reporting period from 01.05.2025 to 30.04.2026, a total of 290,364 products of the Docklocs® Attachment System were placed on the market. Six complaints were documented during the same period. This corresponds to a complaint rate of approximately 0.0021%, or approximately 2.1 complaints per 100,000 products placed on the market. No serious incidents, vigilance reports, or Field Safety Corrective Actions (FSCA) were recorded.

Relative to the estimated 12,850 patients with complete restorations, this corresponds to a rate of approximately 0.047%.

4.1.1.1. Docklocs® Attachment System

Quantitative Overview of Safety-Related Key Figures

Parameter	Result in the Reporting Period
Complaints, of which CAPA-relevant	6 CAPA initiated and closed; 0 open CAPA measures
Serious Incidents (Art. 2 No. 65 MDR)	0
Field Safety Corrective Actions (FSCA)	0
Vigilance Reports (BfArM)	0
PMCF Results with Safety-Relevant Findings	0

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During the reporting period from 01.05.2025 to 30.04.2026, a total of 34,651 straight abutments, 3,899 angled abutments, 148,839 retention inserts, and 98,591 retention housings were placed on the market. The sales figures document the extent of the system's use in the market. Six complaints were documented during the same period. No serious incidents, vigilance reports, or Field Safety Corrective Actions (FSCA) were recorded. Six complaints were documented across a total of more than 290,364 products placed on the market. This corresponds to a complaint rate of <0.01%

Source	Results	Assessment
Customer Feedback Analysis	The analysis revealed no evidence of previously unknown risks, serious incidents, or safety-related trends. The documented feedback related predominantly to general application questions, product-specific information, and support in selecting suitable components. No evidence of systematic product defects or recurring malfunctions was found. In the customer feedback analysed, the handling, retention, and compatibility of the system in particular were highlighted positively. No complaints relating to the safety or clinical performance of the Docklocs® Attachment System were identified during the reporting period. The analysis of customer service call records thus confirms the previous findings from post-market surveillance, risk management, literature search, and complaint management. No new hazards or risks were identified that would require an adaptation of the risk assessment, the clinical evaluation, or the planned PMCF measures. Based on the analysed data, the safety and performance profile of the Docklocs® Attachment System continues to be assessed as positive. The results of the customer feedback support the assumption that the product can be safely used within its intended purpose and delivers the expected clinical performance.	No identifiable residual risk
Complaints	A total of six Corrective and Preventive Actions (CAPA) were initiated, processed, and successfully closed during the reporting period. At the time this report was prepared, there were no open CAPA measures. The analysis of the closed CAPAs shows that identified deviations, potential improvements, and quality-relevant issues were systematically investigated, appropriate measures were defined, and their effectiveness was verified. Processing took place within the established quality management system in accordance with the defined processes. The analysis of the CAPA data revealed no evidence of systematic product defects, recurring failure patterns, or safety-relevant risks in connection with the Docklocs® Attachment System. Furthermore, no findings were obtained that would indicate a deterioration in the safety or performance profile of the product. The complete processing of all initiated CAPA measures, together with the absence of open measures, demonstrates the effectiveness of the implemented quality management system and the continuous improvement process. The results confirm	No evidence of new or previously unknown risks

	that identified issues are appropriately addressed and potential risks are effectively controlled. In summary, the CAPA data provide no evidence of new risks or trends that would require an adaptation of the risk assessment, the clinical evaluation, or the post-market surveillance and PMCF activities. The results support the positive assessment of the safety and performance profile of the Docklocs® Attachment System.	

The PMS data are based on the use of the system in an estimated 12,850 patients with complete restorations, as well as an additional approximately 50,000 patient treatments related to the replacement of retention inserts. The analysis revealed no evidence of new risks, safety-related trends, or a deterioration of the benefit-risk profile.

4.1.1.2. Literature Search

The literature search conducted in the databases PubMed/PubMed Central, DIMDI, BfArM, Google Scholar Central and MAUDE for the preceding 12 months yielded the following results. Results in which the search term could be assigned to the subject area of the Docklocs® Attachment System were considered.

Database	Hits (Number)	Type of Register / Data Collection	Considered	Considered Relevant	Risk acceptable	
					yes	no
PubMed	81	Prospective / Retrospective	16	7	x	
BfArM	No results	Retrospective				
Google Scholar	580	Prospective / Retrospective	16	5	x	
MAUDE	270	Retrospective	270	0	x	

Of a total of 931 identified hits, 12 publications were assessed as clinically relevant and included in the evaluation.

The literature search conducted during the reporting period revealed no evidence of new or previously unknown risks associated with Locator-based attachment systems. The identified publications assessed as relevant continue to confirm the established clinical use of these treatment concepts and their positive benefit-risk ratio.

In particular, the literature describes reliable retention, high user and patient satisfaction, and long-term clinical stability. Furthermore, the advantages of modern materials and design improvements with respect to wear behaviour and long-term stability are highlighted.

The Docklocs® Attachment System is based on the established concept of implant-supported, study-based retention systems for removable dentures and has been optimised through targeted improvements in material selection and design. The results of the literature search confirm that the known clinical advantages of this category of system continue to apply and that there is no evidence indicating a deterioration in the safety or performance profile of the Docklocs® Attachment System.

The results of the literature search were cross-checked against the findings from PMS, vigilance, complaint management and PMCF. No contradictions were found between the fin-

dings from the scientific literature and the actual field data of the Docklocs® Attachment System. The available data confirm the long-established clinical use of implant-supported retention systems for removable dentures.

In summary, the literature search revealed no new safety-related findings. The available data continue to support a positive assessment of the benefit-risk ratio of the Docklocs® Attachment System.

Based on the evaluation of the available data, the residual risk associated with the use of the medical device is to be regarded as low.

4.2. Warnings and Precautions

4.2.1 Warnings and Precautions

The product should be checked for integrity and completeness before use. Products in damaged packaging should not be used on patients. If the packaging is damaged, the damaged packaging should be returned to the manufacturer together with the product. Replacement will only be provided if the packaging damage was caused during shipment of the product.
If the Docklocs implant abutment is subjected to inappropriate loading conditions, there is a potential risk of metal fatigue.

As surgical instruments are susceptible to damage and wear, they should be inspected before each use. Markings should be visible and legible. To ensure proper function, any reusable instrument should be replaced as soon as damage or wear is present. The number of uses varies and depends on a variety of factors, including but not limited to the bone density encountered, handling, proper cleaning, autoclave exposure, and storage conditions (do not store tools or instruments wet). Over time, repeated sterilisation may affect the appearance and visibility of the markings. If this applies to the surgical instrument, check the connection function for wear to ensure the connection is not damaged.

Assessment of the patient, including determination of general state of health, oral hygiene habits and oral hygiene status, motivation for good dental care, and anatomical acceptance, is of crucial importance prior to placement of the implant attachments as part of the restorative process. A thorough assessment of the patient's medical status and history is mandatory. Treatment planning is of critical importance for the success of the implant and the denture.

Always also observe the instructions for use of the implant manufacturers! Some implant manufacturers permit a divergence of only 10° per implant in order to avoid excessive mechanical loading.

Use of this attachment system requires the practitioner to be familiar with the product and the method for its use and application. The clinician must exercise sound judgement in deciding when and where the product should be used.

The individual patient situation should always be taken into account when fabricating the prosthetic restoration. If parafunctions or temporomandibular joint disorders such as bruxism are known, these must always be taken into consideration during treatment.

4.2.2 MRI Safety Information

The Docklocs® Attachment System has not been tested for safety and compatibility in the magnetic resonance (MR) environment. Since no MRI compatibility testing has been performed, potential risks associated with heating, migration or image artefacts cannot be

excluded. The safety of the Docklocs® Attachment System in the MR environment is unknown.

4.2.3 Storage and Handling

There are no special considerations regarding transport and handling for the Docklocs® Attachment System while it remains in its undamaged original packaging. Storage should take place in a dry location at room temperature. Protect from direct sunlight.

4.2.4 Single-Use Products

With the exception of tools and instruments, all components of the Docklocs® Attachment System are single-use products and are supplied non-sterile. Single-use products must not be reused or re-sterilised. If a single-use product is reused, harm may be caused to the patient through the transfer of blood, tissue or saliva, which may contain infectious diseases. Single-use products that are re-sterilised may not function as intended and may result in improper surgical procedure and in malfunction or failure of the product.

Docklocs Retention Inserts: Docklocs retention inserts that are inadvertently reused may result in loss of retention of the overdenture due to wear from prior use or damage sustained during removal with the Docklocs universal instrument.

Docklocs Attachments: Docklocs attachments that are inadvertently reused could cause contamination of the patient, deposits, and consequent wear of the retention inserts. This would result in improper fit and malfunction, leading to loss of retention of the denture.

4.2.5 Disposal

Dispose of used products presenting a risk of infection in accordance with the clinical waste procedures applicable to the respective facility, as well as in accordance with applicable local and national regulations.

4.2.6 Performance Requirements and Limitations

4.2.6.1 Compatibility

The secondary components of the Docklocs® Attachment System may only be combined with the implant systems intended for them.
Check, using the marking on the products or product labels, whether the products are compatible.
The implant systems compatible with the secondary components are listed in the table:
Table 1: Compatible Implant Systems

4.2.6.2 Performance

In order to achieve the intended performance of the Docklocs® Attachment System, products may only be combined with one another as described in the instructions for use. Each product may only be used in accordance with its intended purpose. All parameter specifications given in the instructions for use that are relevant to the respective product must be observed.

4.2.7 Patient Care

Good oral hygiene is essential for success with the Docklocs® Attachment System. The patient should be made aware of the following:

- Docklocs Attachments must be thoroughly cleaned every day to prevent

the build-up of plaque biofilm. To clean the abutments, the patient should use a soft nylon brush or an end-tuft toothbrush with a non-abrasive toothpaste.
- The coarse particles in abrasive toothpastes can scratch the surfaces of the abutments and cause additional plaque accumulation.
- An irrigation system is recommended to rinse residues from the inside of the Docklocs retention inserts.
- The Docklocs retention inserts are manufactured from a flexible plastic material so that overdentures can be removed and replaced on a regular basis. Plastic materials are subject to a certain amount of wear during normal use and may need to be replaced.
- Bruxism (teeth grinding) wears down the Docklocs abutments and can shorten the service life of the retention inserts.

Patients should be instructed to attend regular check-up appointments to review hygiene and attachment function. If a patient experiences discomfort or a loss of retention of the overdenture, they should consult a dentist.
Follow-up visits are recommended at intervals of 6 months. The abutments must be re-tightened at follow-up visits in accordance with the torque specifications given above. Failure to re-tighten the abutments may result in loosening of the screws and fracture of the abutment. Patients should be examined for signs of inflammation around the implant abutments and for implant mobility at every follow-up visit.

4.2.8 Further Information

Conventional restorative protocols should be followed when processing the attachments into the patient's overdenture. Standard care and maintenance of the overdenture should be followed at every repair to ensure its longevity.

4.3. Other Relevant Safety Aspects

Six complaints were analysed during the reporting period. The reported issues concerned two fractures of threaded posts on abutments, one implant-abutment system that became detached from the jaw together during a removal attempt, one deformed retention insert, one reported coating wear, and one incomplete laboratory kit. None of the cases resulted in patient harm, a serious deterioration in state of health, or a serious incident requiring notification under the MDR.

4.4. Summary

As with all implant-supported prosthetic restoration systems, residual risks also exist with the use of the Docklocs® Attachment System that cannot be completely excluded despite the implementation of appropriate risk control measures.

The identified residual risks correspond to the current state of the art and have been assessed as part of the risk management process in accordance with DIN EN ISO 14971. The remaining residual risks are classified as acceptable and are outweighed by the clinical benefit of the product.

Possible residual risks and undesirable effects may include, among others:

- Loosening of implant components or abutments
- Wear of retention inserts as a result of regular use
- Loss of retentive force with long-term use
- Damage to or fracture of denture components in the event of improper use or exceptional loading

- Irritation or hypersensitivity reactions to the materials used in correspondingly predisposed patients
- Discomfort or pressure sores in the area of the prosthetic restoration
- Need for maintenance or replacement measures as part of regular follow-up care

The analysis of clinical data, post-market surveillance (PMS), Post-Market Clinical Follow-up (PMCF) activities, complaints, and available vigilance data revealed no evidence of previously unknown risks or an increase in the frequency of known risks.

No serious incidents attributable to a systematic fault of the Docklocs® Attachment System were identified during the reporting period. The documented complaints were within the expected range for implant-supported attachment systems and did not result in any change to the known safety profile.
Based on the available data, the benefit-risk ratio of the Docklocs® Attachment System continues to be assessed as positive. The clinical benefits with respect to retention, stabilisation, and improved function of implant-supported removable dentures outweigh the remaining residual risks.
The analysis of PMS data, vigilance data, complaints, customer feedback, PMCF activities and the scientific literature revealed no evidence of new risks or safety-related trends. The safety profile of the Docklocs® Attachment System continues to be assessed as positive.
The data collected confirm the safe use of the product within its intended purpose.

5. Summary of the Clinical Evaluation in Accordance with Annex XIV

5.1. Summary of Clinical Data on an Equivalent Product

An equivalence assessment was performed against the original manufacturer Zest Anchors as the reference product. The Docklocs® Attachment System is based on the established concept of a study-supported, implant-supported retention system for removable dentures. The clinical evaluation takes into account data on comparable attachment systems as well as product-specific technical, biological and clinical evidence.
The Locator System was introduced in 2001. There is extensive long-standing clinical experience as well as thorough documentation available on the system.
Many studies and publications show that this system offers numerous advantages over other systems, such as ball attachments and magnetic attachments, for the retention of removable dentures on implants.
To demonstrate the efficacy and safety of a medical device, clinical data from equivalent, CE-marked products may be used. In accordance with Annex A1 of MEDDEV 2.7/1 (Rev. 04) and Annex XIV (Part A) of Regulation 2017/745 (MDR), equivalence is based on clinical, technical and biological aspects. The equivalence assessment was carried out as part of the clinical evaluation.

All relevant data were obtained from studies, instructions for use, surgical and/or prosthetic manuals, as well as system overviews and product catalogues of the manufacturer. The equivalence assessment carried out on the compiled data revealed no differences between the Docklocs products under evaluation and the corresponding products of the Locator System that would be expected to have a negative impact on safety, clinical performance, or clinical benefit.

The available literature describes Locator-based attachment systems as an established treatment option for implant-supported removable dentures. The reported clinical outcomes show reliable retention and high patient satisfaction. The literature data were assessed as part of the clinical evaluation with regard to their relevance to the technical design, biological safety, and clinical performance of the Docklocs® Attachment System. The transferability of the data was substantiated as part of the clinical evaluation.

Comparative studies between Locator-based systems and ball-head systems show differences in wear behaviour and retentive force profile (50: Comparison of changes in retentive force and wear pattern of two stud attachments for implant overdentures: An in vitro study). One of the main criticisms raised in many studies is the excessively rapid loss of retention between the denture and the retentive elements. This is also shown by a study assessing the satisfaction of patients treated with ball-head and Locator systems, in which excessively rapid loss of retention was rated very negatively. Rapid loss of retention can have many different causes. Factors that play a major role include the different materials of the components, how the practitioner performed the work, whether two or four implants were used, and how divergent the implants are relative to one another. Several studies already show the significant influence these factors have on wear and loss of retention. Not least, the patient can also influence wear through their behaviour with respect to preventive care and maintenance. However, the material of the retention inserts certainly has a major influence on wear behaviour. This was also demonstrated in the investigations in the technical documentation comparing the Zest retention inserts and the Docklocs retention inserts. It was found that the Zest retention inserts exhibited a very pronounced loss of retention after 1,000 cycles, which simulates approximately one year of denture wear. This behaviour was not observed for the Docklocs retention inserts, which showed a linear course of retention loss over the required 5,000 cycles and still exhibited a very high retentive force thereafter.
Many studies show that the practitioner also has a very significant influence on the success of a Locator restoration. MEDEALIS supports the practitioner in this regard through its instructions for use and work instructions. Further studies show the significant influence of axis divergence between implants in Locator restorations, which results in premature loss of retention of the plastic inserts and increased wear at the secondary components. Since such divergence cannot always be avoided, it is all the more important that MEDEALIS, through its 18° angled abutments, gives the practitioner the ability to compensate for axis divergence to the greatest extent possible.

5.2. Summary of Clinical Data Prior to CE Marking

Medealis maintains extensive development documentation for its products. The products were examined and assessed for their strength and compatibility with the connection geometries. The materials were investigated and assessed for their biocompatibility. Tests were carried out to demonstrate the durability and function of the retention inserts.
The data obtained are recorded and stored in the development documentation and the technical documentation.

As part of vigilance monitoring, the database of the BfArM (German Federal Institute for Drugs and Medical Devices) is searched once a month for specific issues that could have an impact on the Docklocs® Attachment System.

Monitoring period: monthly since 01.2020

Search terms: Locator, abutment, retention insert, retention housing, dental instrument, dental, implant, Docklocs

To broaden the scope of the search, the terms implant and dental are also included.

For the term implant, only hits with a dental context are included.

No clinical data were identified that have an impact on the safety of the Docklocs® Attachment System.

5.3 Summary of Clinical Data from Other Sources

5.3.1 Literature Search

A comprehensive literature search has been conducted annually in scientific databases since 2018.
In 2018, a literature search on the state of the art in the field of implant prosthetics was conducted for the development of the Docklocs® Attachment System.
Furthermore, continuous literature searches were conducted in the following years and their relevance to the Docklocs® Attachment System was assessed.

	Literature Considered	Assessment
State-of-the-Art Literature Search of 28.04.2018	86 publications	Incorporated into the development of the Docklocs® Attachment System
Literature Search 31.05.2026	32 publications assessed, of which 12 considered relevant Additional review of the MAUDE database for anomalies in reported user issues with Locator abutments.	No indication of an increased risk for the Docklocs® Attachment System is identifiable from the search. The extended search of the MAUDE database shows incidents for which an unambiguous assignment to the Docklocs® Attachment System is not possible.

5.3.2 PMS Data

Medealis has established a post-market surveillance system in accordance with Article 83 of the MDR.
In addition to the evaluation of literature, proactive measures are taken to ensure product safety.
Medealis maintains close contact with its customers. In addition to evaluating customer conversations regarding users' experiences with the Docklocs® Attachment System, a customer survey is conducted once a year, which includes an assessment of the products by the user.
User suggestions are taken up and incorporated into the system where possible.
Medealis operates active complaint management, from which information is obtained and assessed.
Product quality checks are continuously carried out on the products.
All PMS analyses show that, at the present time, no unacceptable risk can be derived for the Docklocs® Attachment System and that the benefit to the patient is given.

The analysis of PMS data for the period from 01.05.2025 to 30.04.2026 included sales figures, complaints, CAPA measures, vigilance data, customer feedback, and findings from Post-Market Clinical Follow-up (PMCF).
No serious incidents, vigilance reports, or field safety corrective actions were recorded during the reporting period. A total of six complaints were documented and assessed. The analysis revealed no evidence of new hazards, risks, or negative trends. The PMS data confirm the findings of the clinical evaluation and support the positive assessment of the benefit-risk ratio of the Docklocs® Attachment System.

5.4 Overall Summary of Clinical Performance and Safety

The Docklocs® Attachment System is based on the established Locator principle and is used for the retention of removable implant-supported full and partial dentures.

The clinical performance of the system consists of the reliable retention and stabilisation of the prosthetic restoration on osseointegrated dental implants, as well as support for masticatory function, phonetics, and patients' quality of life.

The clinical evaluation is based on scientific literature, data on comparable Locator-based attachment systems, results from post-market surveillance (PMS), Post-Market Clinical Follow-up (PMCF), complaint analyses, vigilance data, and the risk management process.

The 2026 literature search covered the databases PubMed, Google Scholar, MAUDE, and other relevant sources. In addition, the search term “Docklocs” was included in the search plan to identify product-specific findings. No new risks, safety concerns, or evidence of a deterioration in the benefit-risk ratio were identified as a result.

The analysis of PMS and PMCF data revealed no evidence of previously unknown hazards or an increase in known risks. The complaints documented during the reporting period were investigated and did not result in any new safety-related findings. No statistically significant negative trend was identified.

The remaining residual risks were assessed as part of risk management and are outweighed by the clinical benefit of the product. The benefit-risk ratio continues to be assessed as positive.

Based on the available clinical evidence, the Docklocs® Attachment System meets the requirements of Regulation (EU) 2017/745 with regard to safety, clinical performance, and clinical benefit.

5.5 Ongoing or Planned Post-Market Clinical Follow-Up

A PMCF plan has been prepared for the clinical follow-up, which is renewed each year or as required. This PMCF plan defines the activities necessary to ensure the clinical performance and safety of the products. The plan was prepared on 28.05.2026. The PMCF evaluation report was prepared on 02.06.2026.

5.6 Status of the Product with Regard to Benefit/Risk Compared to Alternatives

Alternative products were listed in the clinical evaluation, along with their advantages and disadvantages. The body of study evidence regarding the Locator System, to which the Docklocs® Attachment System also belongs, is clear. In the field of elastic retention of removable partial or full dentures on osseointegrated dental implants, the Locator System is to be regarded as widely used and established. The benefit to the patient in relation to the possible risk is supported by numerous studies.

6. Possible Diagnostic or Therapeutic Alternatives

Various implant-supported and conventional prosthetic treatment concepts are available for the restoration of partially or fully edentulous patients. The selection of the appropriate

therapy is made by the treating dentist, taking into account the individual anatomical, functional, and patient-specific circumstances.

Possible alternatives to the Docklocs® Attachment System include, among others:

- conventional removable full or partial dentures without implant support,
- implant-supported restorations with ball attachments,
- implant-supported bar restorations,
- telescopic restorations,
- magnet-supported retention systems,
- fixed implant-supported prosthetic restorations.

The various treatment concepts differ with respect to retention, stability, cleanability, treatment effort, maintenance requirements, and patient comfort.

The Docklocs® Attachment System is intended for the retention of removable implant-supported dentures and offers the possibility of secure anchoring while at the same time allowing the patient to easily remove the denture for daily cleaning and care.

The decision for a specific treatment concept should always be based on the individual clinical situation and following professional advice from qualified dental professionals.

7. Suggested Profile and Training for Users

Use of this attachment system requires the dentist/physician to be familiar with the product and the method for its use and application. The clinician must exercise sound judgement in deciding when and where the product should be used.
The dentist/physician should have knowledge of implantology, as well as in related disciplines such as surgery, periodontology, and prosthetics, since the finished restoration must provide long-term function and aesthetics.

8. Reference to All Applied Harmonised Standards and Common Specifications

Item No.	**Law / Regulation / Standard**	**Version dated**
	Requirements in the Field of Medical Devices (Directives/Laws/Regulations)	
1	Medical Devices Act (Medical Device Law Implementation Act – (MPDG))	28.04.2021 (version dated 12.05.2021)
2	26.05.2021	
4	Ordinance on the Reporting of Suspected Serious Incidents Involving Medical Devices (Medical Device User Reporting and Information Ordinance - MPAMIV)	21.04.2021
5	Regulation (EU) 2017/745 (MDR)	05.04.2017 (Fassung vom 01.01.2026)
	Requirements in the Field of Quality Management/Medical Devices (Standards)	
6	DIN EN ISO 9001:2015 – Quality management systems	Nov. 2015
7	DIN EN ISO 13485:2021 – Quality management systems – Requirements for regulatory purposes (German version)	Dec. 2021

8	DIN EN ISO 14971:2022-04 – Medical devices – Application of risk management to medical devices	Apr. 2022
9	DIN EN ISO 15223-1:2022-02 Medical devices – Symbols to be used with information to be supplied by the manufacturer.	Feb. 2022
10	ISO 20417:2021-04 Medical devices – Information to be supplied by the manufacturer (German version)	Apr. 2021
11	DIN EN ISO 10993-1:2026-03 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process	Mar. 2026
12	DIN EN 62366:2021-08 - Medical devices – Application of usability engineering to medical devices	Jul. 2021
	Guidelines in the Field of Quality Management/Medical Devices (MEDDEV)	
13	MDCG 2023-3 Rev. 2 Questions and Answers on vigilance terms and concepts as outlined in the Regulation (EU) 2017/745 and Regulation (EU) 2017/746 *Replaces MEDDEV 2.12-1*	Oct. 2022
13a	MDCG 2024-1 Guidance on the vigilance system for CE-marked devices	Jan. 2024
13b	MDCG 2020-10/1_Rev.1 Safety reporting in clinical investigations of medical devices under EU 2017/745 *Regulates the reporting of serious adverse events (SAEs) and device deficiencies within clinical investigations*	Oct. 2022
14	MEDDEV 2.12-2 - Guidelines on medical devices - ON POST MARKET CLINICAL FOLLOW-UP STUDIES *Remains partially relevant as a reference document*	Rev.2 2012-01
14a	MDCG 2020-7 PMCF Plan Template *Expands and specifies MEDDEV 2.12-2*	Apr. 2020
14b	MDCG 2020-8: PMCF Evaluation Report Template *Expands and specifies MEDDEV 2.12-2*	Apr. 2020
15	MEDDEV. 2.7/1 CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES *Not replaced, but supplemented and updated by items 15a-15g*	Rev.4 2016-06
15a	MDCG 2019-9_Rev.1 Summary of safety and clinical performance	Mar. 2022
15b	MDCG 2020-1 Guidance on Clinical Evaluation	Mar. 2020
15c	MDCG 2020-5 Clinical Evaluation – Equivalence	Apr. 2020
15d	MDCG 2020-6 Clinical evidence needed for legacy devices	Apr. 2020
15e	MDCG 2020-13 Clinical evaluation assessment report template	Jul. 2020
15f	MDCG 2021-28 Substantial modification of clinical investigation under Medical Device Regulation	Dec. 2021
15g	MDCG 2023-7: Guidance on exemptions from the requirement to perform clinical investigations	Dec. 2023
16	DIN EN ISO 14801:2017-03 Fatigue testing	2017-03
17	DIN EN ISO 5832-3:2022 (Implants for surgery – Metallic materials – Part 3: Wrought titanium 6-aluminium 4-vanadium alloy)	Feb. 2022
18	EN ISO 17664:2021-11 (Processing of health care products – Information to be provided by the medical device manufacturer)	Nov. 2021
19	DIN EN ISO 22674:2023-4 (Dentistry – Metallic materials for fixed and removable restorations and appliances)	Apr. 2023
20	DIN EN ISO 11737-1:2021-10 Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018); German version EN ISO 11737-1:2018	Oct. 2021
21	DIN ISO 2859-1:2014-08 Sampling procedures for inspection by attributes	Aug. 2014
	Further MDCG Guidelines	

22	MDCG 2021-24 Rev.1 Guidance on classification of medical devices	Apr. 2026 (Rev.1)
23	MDCG 2022-14 MDCG Position Paper Transition to the MDR	Aug. 2022
24	MDCG 2019-15 rev.1 GUIDANCE NOTES FOR MANUFACTURERS OF CLASS I MEDICAL DEVICES	July 2020 Rev. 1
25	MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR	Oct. 2019
26	MDCG 2019-7 Rev.1 Guidance on Article 15 of the medical device regulation (MDR) and in vitro diagnostic device regulation (IVDR) on a 'person responsible for regulatory compliance' (PRRC)	Dec. 2023
27	MDCG 2022-21 GUIDANCE ON PERIODIC SAFETY UPDATE REPORT (PSUR) ACCORDING TO REGULATION (EU) 2017/745 (MDR)	Dec. 2022
28	MDCG 2025-10 Guidance on post-market surveillance of medical devices and in vitro diagnostic medical devices	Dec. 2025
29	DIN EN ISO 14155:2026-03 – Clinical investigation of medical devices for human subjects – Good clinical practice	Mar. 2026

9. Revision History

SSCP Revision Number	Date of Issue	Description of Change	Revision Validated by the Notified Body
01	28.02.2022	Creation	☐ Ja Language of validation: German ☒ Nein
02	20.07.2022	Revision of the SSCP report in accordance with the requirements of the Notified Body.	☒ Ja Language of validation: German ☐ Nein
03	27.06.2023	Update	☐ Ja Language of validation: German ☒ Nein
04	20.06.2024	Update	☐ Ja Language of validation: German ☒ Nein
05	30.05.2025	Update of all relevant safety and performance information. English translation added.	☐ Ja Language of validation: German ☒ Nein
06	03.06.2026	Prepared for the assessment period 01.05.2025-30.04.2026	☐ Ja Language of validation: German ☒ Nein