

EU Technical Documentation Assessment Certificate



Medical Devices Regulation (EU) 2017/745 Annex IX
Chapter II and III
Certificate Number: M.2023.MDR.1015-1

Manufacturer Name : Mode Medikal San. ve Tic. Ltd. Şti.
Manufacturer Address : Yenidoğan Mah. Abdi İpekçi Cad. No: 58
Bayrampaşa, İstanbul, Türkiye
Single registration number-SRN : TR-MF-000018719
Authorised Representative Name (If applicable) :-
Authorised Representative Address :-
Product Scope : See the product list on the following page(s).

Based on the assessment of technical documentation for the abovementioned manufacturer in accordance with (EU) 2017/745 Medical Devices Regulation Annex IX Chapter II and Chapter III, UDEM Adriatic d.o.o. hereby declares that the technical documentation of the listed products in this certificate meets the requirements of Annex IX Chapter II and Chapter III of the Regulation (EU) 2017/745. The report referenced below summarizes the result of assessments/examinations and includes reference to relevant CS, harmonized standards and test reports.

For Class III and Class IIb implantable devices referred to in the second subparagraph of Article 52(4) of Regulation (EU) 2017/745, covered by this certificate, an EU Quality Management System Certificate in accordance with (EU) 2017/745 Medical Devices Regulation Annex IX Chapter I and Chapter III is also required before placing them on the market.

The validity of this certificate is dependent on the validity of the accompanying EU Quality Management System Certificate.

Report Number : MDR.1381
Date of Issue : 09/05/2023
Recertification Date :-
Reissue Date/No :-
Date of Expiry : 08/05/2027

UDEM Adriatic d.o.o.
General Manager

If any, Previous Certificate(s) No: -



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PRODUCT LIST COVERED BY THE CERTIFICATE

PRODUCT NAME	BASIC UDI-DI	RISK CLASS	EMDN CODE	MODEL	TYPE	INTENDED PURPOSE
Sterile Substructures-Implants	868061714MODEIMPLANTF6	Class IIb	P01020101	Ø3,3/L8	RAPID NP	Intended to be used in oral implantation as a support for prosthetic applications to be made in order to eliminate the function, phonation and aesthetic problems caused by tooth deficiencies in the lower and/or upper jaw bones.
				Ø3,3/L10		
				Ø3,3/L11,5		
				Ø3,3/L13		
				Ø3,3/L16		
				Ø3,7/L8		
				Ø3,7/L10		
				Ø3,7/L11,5		
				Ø3,7/L13		
				Ø3,7/L16		
				Ø4,1/L8	RAPID RP	
				Ø4,1/L10		
				Ø4,1/L11,5		
				Ø4,1/L13		
				Ø4,1/L16		
				Ø4,7/L8		
				Ø4,7/L10		
				Ø4,7/L11,5		
				Ø4,7/L13		
				Ø4,7/L16		
				Ø5,2/L8	RAPID WP	
				Ø5,2/L10		
				Ø5,2/L11,5		
				Ø5,2/L13		
				Ø5,2/L16		
				Ø5,3/L8	LEVEL NP	
				Ø5,3/L10		
				Ø5,3/L11,5		
				Ø5,3/L13		
				Ø5,3/L16		
				Ø3,3/L8	LEVEL RP	
				Ø3,3/L10		
				Ø3,3/L11,5		
				Ø3,3/L13		
				Ø3,3/L16		
				Ø3,7/L8		
				Ø3,7/L10		
				Ø3,7/L11,5		
				Ø3,7/L13		
				Ø3,7/L16		
Ø4,1/L8	LEVEL RP					
Ø4,1/L10						
Ø4,1/L11,5						
Ø4,1/L13						
Ø4,1/L16						
Ø4,7/L8						

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				Ø4,7/L10			
				Ø4,7/L11,5			
				Ø4,7/L13			
				Ø4,7/L16			
				Ø5,2/L8			
				Ø5,2/L10			
				Ø5,2/L11,5			
				Ø5,2/L13			
				Ø5,2/L16			
				Ø5,3/L8			LEVEL WP
				Ø5,3/L10			
				Ø5,3/L11,5			
				Ø5,3/L13			
				Ø5,3/L16			
				Ø4,1/L8			TISSUE RP
				Ø4,1/L10			
				Ø4,1/L11,5			
				Ø4,1/L13			
				Ø4,1/L16			
				Ø4,7/L8			
				Ø4,7/L10			
				Ø4,7/L11,5			
				Ø4,7/L13			
				Ø4,7/L16			
				Ø5,3/L8			TISSUE WP
				Ø5,3/L10			
				Ø5,3/L11,5			
				Ø5,3/L13			
				Ø5,3/L16			
				Ø6,0/L8			
				Ø6,0/L10			
				Ø6,0/L11,5			
				Ø6,0/L13			
Ø3,3/L8	RIGID (BONE) NP						
Ø3,3/L10							
Ø3,3/L11,5							
Ø3,3/L13							
Ø3,3/L16							
Ø3,7/L8							
Ø3,7/L10							
Ø3,7/L11,5							
Ø3,7/L13							
Ø3,7/L16							
Ø4,1/L8	RIGID (BONE) RP						
Ø4,1/L10							
Ø4,1/L11,5							
Ø4,1/L13							
Ø4,1/L16							
Ø4,7/L8							
Ø4,7/L10							
Ø4,7/L11,5							
Ø4,7/L13							

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				Ø4,7/L16		
				Ø3,7/L6	SHORT IMPLANT NP	
				Ø4,1/L6	SHORT IMPLANT RP	
				Ø4,7/L6		
				Ø5,2/L6	SHORT IMPLANT WP	
				Ø5,3/L6		
				Ø6,0/L6		
				Ø3,7/L5	SHORTER IMPLANT NP	
				Ø4,1/L5	SHORTER IMPLANT	
				Ø4,7/L5		
				Ø5,2/L5		
				Ø5,3/L5	SHORTER IMPLANT WP	
				Ø6,0/L5		
				Ø2,5/L10	PROVO IMPLANT	
				Ø2,5/L12		
				Ø2,5/L15		
				Ø3,0/L8		
				Ø3,0/L10		
				Ø3,0/L12		
				Ø3,0/L15		
				Ø3,5/L8		
				Ø3,5/L10		
				Ø3,5/L12		
				Ø3,5/L15		
				Ø4,0/L8		
				Ø4,0/L10		
				Ø4,0/L12		
				Ø4,0/L15		
				Ø4,5/L8		
				Ø4,5/L10		
				Ø4,5/L12		
				Ø4,5/L15		
				Ø2,2/L10	MINI IMPLANT	
				Ø2,2/L12		
				Ø2,2/L14		
				Ø2,5/L10		
				Ø2,5/L12		
				Ø2,5/L14		
				Ø2,9/L8		
				Ø2,9/L10		
				Ø2,9/L12		
				Ø2,9/L14		

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Sterile Superstructures - Abutment	868061714MODEABUTMENTAX	Class IIb	P01020180	-	COVER SCREW NP	They are intended to use with the relevant Mode dental implants in the lower and/or upper jaws in partially or completely edentulous patients by covering the implant-abutment connection for preventing soft and hard tissue growth in this area during the healing process area in cases where two-stage surgical technique is used.
				-	COVER SCREW RP	
				-	COVER SCREW WP	
Non-Sterile Superstructures - Abutment				Ø3,5/H0,5	DIRECT ABUTMENT NP	They are attached directly to the intraosseous implants with the help of abutment screws in order to support the implant-supported cement retained fixed prostheses
				Ø3,5/H1		
				Ø3,5/H2		
				Ø3,5/H3		
				Ø3,5/H4		
				Ø4,0/H0,5		
				Ø4,0/H1		
				Ø4,0/H2		
				Ø4,0/H3		
				Ø4,0/H4		
				Ø4,5/H0,5	DIRECT ABUTMENT RP	
				Ø4,5/H1		
				Ø4,5/H2		
				Ø4,5/H3		
				Ø4,5/H4		
				Ø5,0/H0,5		
				Ø5,0/H1		
				Ø5,0/H2		
				Ø5,0/H3	DIRECT ABUTMENT WP	
				Ø5,0/H4		
Ø5,0/H0,5						
Ø5,0/H1						
Ø5,0/H2						
Ø5,0/H3						
Ø5,0/H4						
Ø6,0/H0,5						

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				Ø6,0/H1			
				Ø6,0/H2			
				Ø6,0/H3			
				Ø6,0/H4			
				15°/H1	ESTHETIC ABUTMENT NP		
				15°/H2			
				15°/H3			
				15°/H4			
				15°/H1	ESTHETIC ABUTMENT RP		
				15°/H2			
				15°/H3			
				15°/H4			
				15°/H1	ESTHETIC ABUTMENT WP		
				15°/H2			
				15°/H3			
				15°/H4			
				25°/H1	ESTHETIC ABUTMENT NP		
				25°/H2			
				25°/H3			
				25°/H4			
				25°/H1	ESTHETIC ABUTMENT RP		
				25°/H2			
				25°/H3			
				25°/H4			
				25°/H1	ESTHETIC ABUTMENT WP		
				25°/H2			
				25°/H3			
				25°/H4			
				H1	ESTHETIC ABUTMENT NP		
				H2			
				H3			
				H1	ESTHETIC ABUTMENT RP		
				H2			
				H3			
				H1	ESTHETIC ABUTMENT WP		
				H2			
				H3			
				H0,5	MULTI UNIT ABUTMENT NP		
				H1			
				H2			
				H3			
				H4			
				H0,5	MULTI UNIT ABUTMENT RP		
				H1			
				H2			
				H3			
				H4			
				H0,5	MULTI UNIT ABUTMENT WP		
				H1			
				H2			
				H3			
				H4			

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				H2,5	17° MULTI BASE ABUTMENT NP	
				H3,5	17° MULTI BASE ABUTMENT RP	
				H2,5	17° MULTI BASE ABUTMENT WP	
				H3,5	30° MULTI BASE ABUTMENT NP	
				H4	30° MULTI BASE ABUTMENT RP	
				H3,5	30° MULTI BASE ABUTMENT WP	
				H1	MULTI BASE LOCATOR COVER	
				H2	MULTI BASE BALL COVER	
				-	MULTI BASE COVER	
				-	MULTI TEMPORARY ABUTMENT	
				-	TI-BASE MULTI ENGAGE	
				-	TI-BASE MULTI NON ENGAGE	
				M1,8	PROSTHETIC SCREW	Intended to be used to fix patient-specific temporary or permanent crowns to the relevant abutments.
				M1,6	ABUTMENT SCREW NP/RP	They are attached directly to the intraosseous implants with the help of abutment screws in order to support the
				M1,8	ABUTMENT SCREW WP	

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						implant-supported cement retained fixed prostheses.
				H0,5	BALL ABUTMENT NP	Used to support dentures in order to fulfill the chewing function and to eliminate tooth deficiencies. One-piece Ball Abutments are screwed to MODE medical implants and form a basis for overdenture structures.
				H1		
				H2		
				H3		
				H4		
				H6		
				H0,5	BALL ABUTMENT RP	Used to support dentures in order to fulfill the chewing function and to eliminate tooth deficiencies. One-piece Ball Abutments are screwed to MODE medical implants and form a basis for overdenture structures.
				H1		
				H2		
				H3		
				H4		
				H6		
				-	BALL ABUTMENT METAL CAP	Used to support dentures in order to fulfill the chewing function and to eliminate tooth deficiencies. One-piece Ball Abutments are screwed to MODE medical implants and form a basis for overdenture structures.
				H0,5	LOCATOR ABUTMENT NP	They are attached directly to the intraosseous implants with the help of abutment screws in order to support the implant-supported cement retained fixed prostheses.
				H1		
				H2		
				H3		
				H4		
				H6		
				H0,5	LOCATOR ABUTMENT RP	They are attached directly to the intraosseous implants with the help of abutment screws in order to support the implant-supported cement retained fixed prostheses.
				H1		
				H2		
				H3		
				H4		
				H6		
				H1	PROFILE ABUTMENT NP	They are attached directly to the intraosseous implants with the help of abutment screws in order to support the implant-supported cement retained fixed prostheses.
				H2	PROFILE ABUTMENT RP	
				H3	PROFILE ABUTMENT WP	
				H1	PROFILE ABUTMENT NP	
				H2	PROFILE ABUTMENT RP	
				H3	PROFILE ABUTMENT WP	
				-	PREMILL ABUTMENT NP	They are attached directly to the intraosseous implants with the help of abutment screws in order to support the implant-supported cement retained fixed prostheses.
				-	PREMILL ABUTMENT RP	
				-	PREMILL ABUTMENT WP	
				H0,7	TI BASE	

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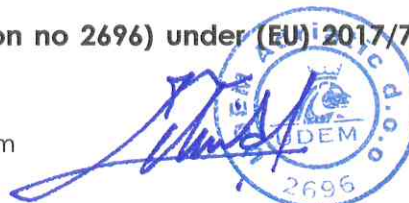
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					NON-ENGAGE NP	
				H0,7	TI BASE NON-ENGAGE RP	
				H0,7	TI BASE NON-ENGAGE WP	
				H2,5	TI BASE NON-ENGAGE NP	
				H2,5	TI BASE NON-ENGAGE RP	
				H2,5	TI BASE NON-ENGAGE WP	
				H0,7	TI BASE ENGAGE NP	
				H0,7	TI BASE ENGAGE RP	
				H0,7	TI BASE ENGAGE WP	
				H2,5	TI BASE ENGAGE NP	
				H2,5	TI BASE ENGAGE RP	
				H2,5	TI BASE ENGAGE WP	
			P01020180	Ø4,0/H2	HEALING ABUTMENT NP	Intended to use for supporting gingival healing on the implant and providing soft tissue contouring by placing them on the corresponding Mode Dental Implants.
				Ø4,0/H4		
				Ø4,0/H6		
				Ø4,5/H2		
				Ø4,5/H4		
				Ø4,5/H6		
				Ø4,5/H2	HEALING ABUTMENT RP	
				Ø4,5/H4		
				Ø4,5/H6		
				Ø5,0/H2		
				Ø5,0/H4		
				Ø5,0/H6		
				Ø5,5/H2	HEALING ABUTMENT WP	
				Ø5,5/H4		
				Ø5,5/H6		
				Ø6,0/H2		
				Ø6,0/H4		
				Ø6,0/H6		
				Ø6,5/H2		
				Ø6,5/H4		
			Ø6,5/H6			

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			P01020180	H0,7	TI BASE NP-S CEREC	They are attached directly to the intraosseous implants with the help of abutment screws in order to support the implant-supported cement retained fixed prostheses.
				H2,5		
				H0,7	TI BASE RP-L CEREC	
				H2,5		
				H0,7	TI BASE WP-L CEREC	
				H2,5		
				H1,5	IMMEDIATE TEMPORARY ABUTMENT NP	
				H3		
				H1,5	IMMEDIATE TEMPORARY ABUTMENT RP	
				H3		
				H1,5	TEMPORARY ABUTMENT ENGAGE NP	
				H1,5	TEMPORARY ABUTMENT ENGAGE RP	
				H1,5	TEMPORARY ABUTMENT ENGAGE WP	
				H1,5	TEMPORARY ABUTMENT ENGAGE NP	
H1,5	TEMPORARY ABUTMENT NON-ENGAGE RP					

Conditions for or limitations to the validity of this certificate : none

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CERTIFICATE HISTORY

Rev. No.	Rev. Date	Description of Revision
00	09/05/2023	Initial Certification

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