

EU Quality Management System Certificate

Medical Devices Regulation (EU) 2017/745 Annex IX
Chapter I and III (Class IIa, IIb and III Devices)



Certificate Number: M.2024.MDR.1037

Manufacturer Name : Dentimplant Medikal Sağlık İç Dış Ticaret Sanayi Anonim Şirketi
Manufacturer Address : Ostim Osb Mah. 1269 Cad. No:17 Yenimahalle, Ankara, Türkiye
Single registration number-SRN : TR-MF-000018370
Authorised Representative Name (If applicable) : NA
Authorised Representative Address : NA
Product Scope : See the product list on the following page(s).

Based on the conformity assessment for the abovementioned manufacturer's quality management system in accordance with (EU) 2017/745 Medical Devices Regulation Annex IX Chapter I and Chapter III, UDEM Adriatic d.o.o. hereby declares that the requirements of Annex IX (Chapter I and Chapter III) of the Regulation (EU) 2017/745 have been met for the listed products in this certificate.

The manufacturer has established, documented and implemented a quality management system, which is subject to periodic surveillance assessments by UDEM Adriatic d.o.o. according to Annex IX Chapter I Section 3 of the aforementioned Regulation.

The report referenced below summarizes the results 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 Technical Documentation Assessment Certificate is required before placing them on the market.

Report Number : MDR.1423
Date of First Issue : 08.05.2024
Recertification Date : -
Revision Date/No : 06.03.2026/02
Date of Expiry : 07.05.2028

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, Dentcon Dental Implants	868113706IMXU	Class IIb	P01020101	Conical Connection Implant Ø3,5 L:6, Ø3,5 L:8, Ø3,5 L:10, Ø3,5 L:11,5, Ø3,5 L:13, Ø3,5 L:15, Ø4 L:6, Ø4 L:8, Ø4 L:10, Ø4 L:11,5, Ø4 L:13, Ø4 L:15, Ø4,5 L:6, Ø4,5 L:8, Ø4,5 L:10, Ø4,5 L:11,5, Ø4,5 L:13, Ø4,5 L:15, Ø5 L:6, Ø5 L:8, Ø5 L:10, Ø5 L:11,5, Ø5 L:13, Ø5 L:15	Intended to be used to replace missing teeth as a support for prosthetic applications to be made in order to eliminate the function, aesthetic problems caused by tooth deficiencies in the lower and/or upper jaw bones.
				Implant Transfer Part	Intended to use to carry the implant from package to the socket.
			P01020180	Implant Cover Screw Ø 4,5, Ø 7	Intended to be used as a cover on the top of the implant as a flat head screw gets placed inside to ensure the gum is completely covered and enables healing without complications.
Sterile, Mitcon Dental Implants	868113706IMXU	Class IIb	P01020101	Conical Connection Implant Ø3,5 L:6, Ø3,5 L:8, Ø3,5 L:10, Ø3,5 L:11,5, Ø3,5 L:13, Ø3,5 L:15, Ø4 L:6, Ø4 L:8, Ø4 L:10, Ø4 L:11,5, Ø4 L:13, Ø4 L:15, Ø4,5 L:6, Ø4,5 L:8, Ø4,5 L:10, Ø4,5 L:11,5, Ø4,5 L:13, Ø4,5 L:15, Ø5 L:6, Ø5 L:8, Ø5 L:10, Ø5 L:11,5, Ø5 L:13, Ø5 L:15	Intended to be used to replace missing teeth as a support for prosthetic applications to be made in order to eliminate the function, aesthetic problems caused by tooth deficiencies in the lower and/or upper jaw bones.
				Implant Transfer Part	Intended to use to carry the implant from package to the socket.
			P01020180	Implant Cover Screw Ø 4,5, Ø 7	Intended to be used as a cover on the top of the implant as a flat head screw gets

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					placed inside to ensure the gum is completely covered and enables healing without complications.
Sterile, Kingimplant Dental Implants	868113706IMXU	Class IIb	P01020101	Conical Connection Implant Ø3,5 L:6, Ø3,5 L:8, Ø3,5 L:10, Ø3,5 L:11,5, Ø3,5 L:13, Ø3,5 L:15, Ø4 L:6, Ø4 L:8, Ø4 L:10, Ø4 L:11,5, Ø4 L:13, Ø4 L:15, Ø4,5 L:6, Ø4,5 L:8, Ø4,5 L:10, Ø4,5 L:11,5, Ø4,5 L:13, Ø4,5 L:15, Ø5 L:6, Ø5 L:8, Ø5 L:10, Ø5 L:11,5, Ø5 L:13, Ø5 L:15	Intended to be used to replace missing teeth as a support for prosthetic applications to be made in order to eliminate the function, aesthetic problems caused by tooth deficiencies in the lower and/or upper jaw bones.
				Implant Transfer Part	Intended to use to carry the implant from package to the socket.
			P01020180	Implant Cover Screw Ø 4,5, Ø 7	Intended to be used as a cover on the top of the implant as a flat head screw gets placed inside to ensure the gum is completely covered and enables healing without complications.
Sterile, Wizimplant Dental Implants	868113706IMXU	Class IIb	P01020101	Conical Connection Implant Ø3,5 L:6, Ø3,5 L:8, Ø3,5 L:10, Ø3,5 L:11,5, Ø3,5 L:13, Ø3,5 L:15, Ø4 L:6, Ø4 L:8, Ø4 L:10, Ø4 L:11,5, Ø4 L:13, Ø4 L:15, Ø4,5 L:6, Ø4,5 L:8, Ø4,5 L:10, Ø4,5 L:11,5, Ø4,5 L:13, Ø4,5 L:15, Ø5 L:6, Ø5 L:8, Ø5 L:10, Ø5 L:11,5, Ø5 L:13, Ø5 L:15	Intended to be used to replace missing teeth as a support for prosthetic applications to be made in order to eliminate the function, aesthetic problems caused by tooth deficiencies in the lower and/or upper jaw bones.
				Implant Transfer Part	Intended to use to carry the implant from package to the socket.
			P01020180	Implant Cover Screw Ø 4,5, Ø 7	Intended to be used as a cover on the top of the implant as a flat head screw gets

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					placed inside to ensure the gum is completely covered and enables healing without complications.
Non-Sterile, Denticon Abutments	868113706ABWE	Class IIb	P01020180	Conical Connection Milling Abutment 0° Standard GH9, 0° Standard GH15, 0° Standard GH12, 0° Wide GH12, 0° Narrow GH12, 15° Standard GH12, 25° standard GH12	To connect the dental implant and the artificial prosthesis with a screw for different indications such as fixed or removable crowns, cemented or screwed prosthesis types.
				Conical Connection Straight Abutment 0° Ø4,5 GH1, 0° Ø4,5 GH2, 0° Ø4,5 GH3, 0° Ø4,5 GH4, 0° Ø5,5 GH1, 0° Ø5,5 GH2, 0° Ø5,5 GH3, 0° Ø5,5 GH4, 0° Ø6,5 GH1, 0° Ø6,5 GH2, 0° Ø6,5 GH3, 0° Ø6,5 GH4	
				Conical Connection Aesthetic Straight Abutment 0° GH1, 0° GH2, 0° GH3, 0° GH4	
				Conical Connection Aesthetic Angled Abutment 15° GH1, 15° GH2, 15° GH3, 15° GH4, 25° GH1, 25° GH2, 25° GH3, 25° GH4	
				Conical Connection Angled Abutment 15° Ø4,5 GH1, 15° Ø4,5 GH2, 15° Ø4,5 GH3, 15° Ø4,5 GH4, 25° Ø4,5 GH1, 25° Ø4,5 GH2, 25° Ø4,5 GH3, 25° Ø4,5 GH4, 15° Ø5,5 GH1, 15° Ø5,5 GH2, 15° Ø5,5 GH3, 15° Ø5,5 GH4, 25° Ø5,5 GH1, 25° Ø5,5 GH2, 25° Ø5,5 GH3, 25° Ø5,5 GH4	
Conical Connection Multi Unit Straight Abutment 0° GH1, 0° GH2, 0° GH3, 0° GH4, 0° GH5, 0° GH7					
				Conical Connection	

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				MultiUnit Anti Rotation Abutment 0° GH1, 0° GH3	
				Conical Connection Multi Unit Angled Abutment 17° GH1, 17° GH3, 30° GH1, 30° GH3	
				Multi-Unit Temporary Abutment	
				Conical Connection Ti-Base Abutment Hex GH0.5, GH1.5, GH2.5	
				Conical Connection Ti-Base Abutment Non Hex GH0.5, GH1.5, GH2.5	
				Multi-Unit Ti-Base Abutment	
				Locator Abutment GH1, GH2, GH3, GH4, GH5, GH7	
				Ball Abutment GH1, GH2, GH3, GH4, GH5, GH7	
				Conical Connection Pre-Milled Abutment Anti Rotational	
				Conical Connection Pre-Milled Abutment Rotational	
				Castable Abutment Rotational (Titanium)	
				Castable Abutment Anti Rotational (Titanium)	
				Dentex Ball Abutment GH1, GH2, GH3, GH4, GH5, GH7	
				Dentex Ti-Base Abutment (Hex) GH1, GH3	
				Dentex Locator GH1, GH2, GH3, GH5, GH7	
				Dentex Pre Milled Abutment Rotational	
				Dentex Pre Milled Abutment Anti Rotational	

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				<p>Dentex Milling Abutment 0° Standard GH9 , 0° Standard GH15 , 0° Standard GH12, 0° Wide GH12, 0° Narrow GH12, 15° Standard GH12, 25° standard GH12</p>
				<p>Dentex Straight Abutment 0° Ø4,5 GH1, 0° Ø4,5 GH2, 0° Ø4,5 GH3, 0° Ø4,5 GH4, 0° Ø5,5 GH1, 0° Ø5,5 GH2, 0° Ø5,5 GH3, 0° Ø5,5 GH4, 0° Ø6,5 GH1 , 0° Ø6,5 GH2 , 0° Ø6,5 GH3 , 0° Ø6,5 GH4</p>
				<p>Dentex Aesthetic Straight Abutment 0° GH1, 0° GH2, 0° GH3, 0° GH4</p>
				<p>Dentex Aesthetic Angled Abutment 15° GH1, 15° GH2, 15° GH3, 15° GH4, 25° GH1, 25° GH2, 25° GH3, 25° GH4</p>
				<p>Dentex Angled Abutment 15° Ø4,5 GH1, 15° Ø4,5 GH2, 15° Ø4,5 GH3, 15° Ø4,5 GH4, 25° Ø4,5 GH1, 25° Ø4,5 GH2, 25° Ø4,5 GH3, 25° Ø4,5 GH4, 15° Ø5,5 GH1, 15° Ø5,5 GH2, 15° Ø5,5 GH3, 15° Ø5,5 GH4, 25° Ø5,5 GH1, 25° Ø5,5 GH2, 25° Ø5,5 GH3, 25° Ø5,5 GH4</p>
				<p>Dentex Multi Unit Straight Abutment 0° GH1, 0° GH2, 0° GH3, 0° GH4, 0° GH5, 0° GH7</p>
				<p>Dentex Multi Unit Angled Abutment 17° GH1, 17° GH3, 30° GH1, 30° GH3</p>
				<p>Dentex Multi-Unit Anti Rotation Abutment 0° GH1, 0° GH3</p>
				<p>Dentex Castable Abutment Rotational (Titanium)</p>
				<p>Dentex Castable Abutment</p>

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				Anti Rotational (Titanium)	
	868113706MCXL	Class IIb	P01020180	Locator Cap Metal Ball Abutment Metal Housing	The housing which plastic cap fits inside for the removable prosthesis.
	868113706SCY6	Class IIb	P01020180	Multi-Unit Abutment Screw GH1, GH3 Multi-Unit Angled Abutment Screw Long, Short Abutment Screw	Intended to be used to fix individual prosthetic or impression pieces to the relevant parts.
Non-Sterile, Mitcon Abutments	868113706ABWE	Class IIb	P01020180	Conical Connection Milling Abutment 0° Standard GH9, 0° Standard GH15, 0° Standard GH12, 0° Wide GH12, 0° Narrow GH12, 15° Standard GH12, 25° Standard GH12 Conical Connection Straight Abutment 0° Ø4,5 GH1, 0° Ø4,5 GH2, 0° Ø4,5 GH3, 0° Ø4,5 GH4, 0° Ø5,5 GH1, 0° Ø5,5 GH2, 0° Ø5,5 GH3, 0° Ø5,5 GH4, 0° Ø6,5 GH1, 0° Ø6,5 GH2, 0° Ø6,5 GH3, 0° Ø6,5 GH4 Conical Connection Aesthetic Straight Abutment 0° GH1, 0° GH2, 0° GH3, 0° GH4 Conical Connection Aesthetic Angled Abutment 15° GH1, 15° GH2, 15° GH3, 15° GH4, 25° GH1, 25° GH2, 25° GH3, 25° GH4 Conical Connection Angled Abutment 15° Ø4,5 GH1, 15° Ø4,5 GH2, 15° Ø4,5 GH3, 15° Ø4,5 GH4, 25° Ø4,5 GH1, 25° Ø4,5 GH2, 25° Ø4,5 GH3, 25° Ø4,5 GH4, 15° Ø5,5 GH1, 15° Ø5,5 GH2, 15° Ø5,5 GH3, 15° Ø5,5 GH4, 25° Ø5,5 GH1, 25° Ø5,5 GH2, 25° Ø5,5 GH3,	To connect the dental implant and the artificial prosthesis with a screw for different indications such as fixed or removable crowns, cemented or screwed prosthesis types.

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				25° Ø5,5 GH4	
				Conical Connection Multi Unit Straight Abutment 0° GH1, 0° GH2, 0° GH3, 0° GH4, 0° GH5, 0° GH7	
				Conical Connection Multi Unit Anti Rotation Abutment 0° GH1, 0° GH3	
				Conical Connection Multi Unit Angled Abutment 17° GH1, 17° GH3, 30° GH1, 30° GH3	
				Multi-Unit Temporary Abutment	
				Conical Connection Ti-Base Abutment Hex GH1, GH3	
				Conical Connection Ti-Base Abutment Non Hex GH1, GH3	
				Multi-Unit Ti-Base Abutment	
				Locator Abutment GH1, GH2, GH3, GH5, GH7	
				Ball Abutment GH1, GH2, GH3, GH4, GH5, GH7	
				Conical Connection Pre-Milled Abutment Anti Rotational	
				Conical connection Pre-Milled Abutment Rotational	
				Castable Abutment Rotational (Titanium)	
				Castable Abutment Anti Rotational (Titanium)	
	868113706MCXL	Class IIb	P01020180	Locator Cap Metal	The housing which plastic cap fits inside for the removable prosthesis.
				Ball Abutment Metal Housing	
	868113706SCY6	Class IIb	P01020180	Multi-Unit Abutment Screw GH1, GH3	Intended to be used to fix individual prosthetic or
				Multi-Unit Angled Abutment	

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				Screw Long, Short	impression pieces to the relevant parts.
				Abutment Screw	
Non-Sterile, Kingimplant Abutments	868113706ABWE	Class IIb	P01020180	Conical Connection Milling Abutment 0° Standard GH9, 0° Standard GH15, 0° Standard GH12, 0° Wide GH12, 0° Narrow GH12, 15° Standard GH12, 25° Standard GH12	To connect the dental implant and the artificial prothesis with a screw for different indications such as fixed or removable crowns, cemented or screwed prothesis types.
				Conical Connection Straight Abutment 0° Ø4,5 GH1, 0° Ø4,5 GH2, 0° Ø4,5 GH3, 0° Ø4,5 GH4, 0° Ø5,5 GH1, 0° Ø5,5 GH2, 0° Ø5,5 GH3, 0° Ø5,5 GH4, 0° Ø6,5 GH1, 0° Ø6,5 GH2, 0° Ø6,5 GH3, 0° Ø6,5 GH4	
				Conical Connection Aesthetic Straight Abutment 0° GH1, 0° GH2, 0° GH3, 0° GH4	
				Conical Connection Aesthetic Angled Abutment 15° GH1, 15° GH2, 15° GH3, 15° GH4, 25° GH1, 25° GH2, 25° GH3, 25° GH4	
				Conical Connection Angled Abutment 15° Ø4,5 GH1, 15° Ø4,5 GH2, 15° Ø4,5 GH3, 15° Ø4,5 GH4, 25° Ø4,5 GH1, 25° Ø4,5 GH2, 25° Ø4,5 GH3, 25° Ø4,5 GH4, 15° Ø5,5 GH1, 15° Ø5,5 GH2, 15° Ø5,5 GH3, 15° Ø5,5 GH4, 25° Ø5,5 GH1, 25° Ø5,5 GH2, 25° Ø5,5 GH3, 25° Ø5,5 GH4	
				Conical Connection Multi Unit Straight Abutment 0° GH1, 0° GH2, 0° GH3, 0° GH4, 0° GH5, 0° GH7	
				Conical Connection Multi Unit Anti Rotation Abutment	

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				0° GH1, 0° GH3	
				Conical Connection Multi Unit Angled Abutment 17° GH1, 17° GH3, 30° GH1, 30° GH3	
				Multi-Unit Temporary Abutment	
				Conical Connection Ti-Base Abutment Hex GH1, GH3	
				Conical Connection Ti-Base Abutment Non Hex GH1, GH3	
				Multi-Unit Ti-Base Abutment	
				Locator Abutment GH1, GH2, GH3, GH5, GH7	
				Ball Abutment GH1, GH2, GH3, GH4, GH5, GH7	
				Conical Connection Pre-Milled Abutment Anti Rotational	
				Conical connection Pre-Milled Abutment Rotational	
				Castable Abutment Rotational (Titanium)	
				Castable Abutment Anti Rotational (Titanium)	
	868113706MCXL	Class IIb	P01020180	Locator Cap Metal Ball Abutment Metal Housing	The housing which plastic cap fits inside for the removable prosthesis.
	868113706SCY6	Class IIb	P01020180	Multi-Unit Abutment Screw GH1, GH3 Multi-Unit Angled Abutment Screw Long, Short Abutment Screw	Intended to be used to fix individual prosthetic or impression pieces to the relevant parts.
Non-Sterile, Wziimplant Abutments	868113706ABWE	Class IIb	P01020180	Conical Connection Milling Abutment 0° Standard GH9, 0° Standard GH15, 0° Standard GH12, 0° Wide GH12, 0° Narrow GH12, 15°	To connect the dental implant and the artificial prosthesis with a screw for different indications such as fixed or

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				Standard GH12, 25° Standard GH12	removable crowns, cemented or screwed prosthesis types.
				Conical Connection Straight Abutment 0° Ø4,5 GH1, 0° Ø4,5 GH2, 0° Ø4,5 GH3, 0° Ø4,5 GH4, 0° Ø5,5 GH1, 0° Ø5,5 GH2, 0° Ø5,5 GH3, 0° Ø5,5 GH4, 0° Ø6,5 GH1, 0° Ø6,5 GH2, 0° Ø6,5 GH3, 0° Ø6,5 GH4	
				Conical Connection Aesthetic Straight, 0° GH1, 0° GH2, 0° GH3, 0° GH4	
				Conical Connection Aesthetic Angled Abutment 15° GH1, 15° GH2, 15° GH3, 15° GH4, 25° GH1, 25° GH2, 25° GH3, 25° GH4	
				Conical Connection Angled Abutment 15° Ø4,5 GH1, 15° Ø4,5 GH2, 15° Ø4,5 GH3, 15° Ø4,5 GH4, 25° Ø4,5 GH1, 25° Ø4,5 GH2, 25° Ø4,5 GH3, 25° Ø4,5 GH4, 15° Ø5,5 GH1, 15° Ø5,5 GH2, 15° Ø5,5 GH3, 15° Ø5,5 GH4, 25° Ø5,5 GH1, 25° Ø5,5 GH2, 25° Ø5,5 GH3, 25° Ø5,5 GH4	
				Conical Connection Multi Unit Straight Abutment 0° GH1, 0° GH2, 0° GH3, 0° GH4, 0° GH5, 0° GH7	
				Conical Connection Multi Unit Anti Rotation Abutment 0° GH1, 0° GH3	
				Conical Connection Multi Unit Angled Abutment 17° GH1, 17° GH3, 30° GH1, 30° GH3	
				Multi-Unit Temporary Abutment	
				Conical Connection Ti-Base Abutment Hex GH1, GH3	

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				Conical Connection Ti-Base Abutment Non Hex GH1, GH3	
				Multi-Unit Ti-Base Abutment	
				Locator Abutment GH1, GH2, GH3, GH5, GH7	
				Ball Abutment GH1, GH2, GH3, GH4, GH5, GH7	
				Conical Connection Pre-Milled Abutment Anti Rotational	
				Conical Connection Pre-Milled Abutment Rotational	
				Castable Abutment Rotational (Titanium)	
				Castable Abutment Anti Rotational (Titanium)	
	868113706MCXL	Class IIb	P01020180	Locator Cap Metal	The housing which plastic cap fits inside for the removable prosthesis.
				Ball Abutment Metal Housing	
	868113706SCY6	Class IIb	P01020180	Multi Unit Abutment Screw GH1, GH3	Intended to be used to fix individual prosthetic or impression pieces to the relevant parts.
				Multi Unit Angled Abutment Screw Long, Short	
				Abutment Screw	

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

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CERTIFICATE HISTORY		
Revision No	Revision Date	Description of Revision
00	08.05.2024	Initial Certification
01	16.02.2026	T The company's legal entity name has been changed from Ltd. Šti. to A.Š The head office address has been changed. Dentcon Locator abutment GH4 added Dentcon Ti-base abutment GH sizes are updated
02	06.03.2026	Basic UDI-DI numbers have been corrected Two codes have been added. 868113706MCXL 868113706SCY6



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