

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.1038

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 : 07.05.2029

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
Non-Sterile, Dentcon Abutments	868113706GFX8	Class IIa	P01020180	Conical Connection Gingiva Former Ø5,5 GH2, Ø5,5 GH3, Ø5,5 GH5, Ø5,5 GH7, Ø5,5 GH9, Ø4,5 GH2, Ø4,5 GH3, Ø4,5 GH5, Ø4,5 GH7, Ø4,5 GH9, Ø6,5 GH2, Ø6,5 GH3, Ø6,5 GH5, Ø6,5 GH7, Ø6,5 GH9, Ø7,5 GH2, Ø7,5 GH3, Ø7,5 GH5, Ø7,5 GH7, Ø7,5 GH9, Ø8,5 GH2, Ø8,5 GH3, Ø8,5 GH5, Ø8,5 GH7, Ø8,5 GH9	Intended to use for supporting gingival healing on the implant and providing soft tissue contouring by placing them on the corresponding implants
				Multi-Unit Gingiva Former	
				Dentex Gingiva Former Ø5,5 GH2, Ø5,5 GH3, Ø5,5 GH5, Ø5,5 GH7, Ø5,5 GH9, Ø4,5 GH9, Ø4,5 GH2, Ø4,5 GH3, Ø4,5 GH5, Ø4,5 GH7, Ø6,5 GH2, Ø6,5 GH3, Ø6,5 GH5, Ø6,5 GH7, Ø6,5 GH9, Ø7,5 GH2, Ø7,5 GH3, Ø7,5 GH5, Ø7,5 GH7, Ø7,5 GH9, Ø8,5 GH2, Ø8,5 GH3, Ø8,5 GH5, Ø8,5 GH7, Ø8,5 GH9	
	868113706TCY9	Class IIa	P01020180	Conical Connection Transfer Open Tray, Closed Tray, Non-Screw	To use to take impression of the exact position of the implant in the patient's mouth and the relationship to the rest of the teeth.
				Multi-Unit Transfer Open Tray, Closed Tray, Closed Tray Hex	
				Dentex Open Tray Transfer	
				Dentex Closed Tray Transfer	
	868113706SBY4	Class IIa	P01020180	Scan Body	To be used in digital dentistry to capture accurate digital impressions of patients' oral structures.
				Multi-Unit Scan Body	
				Multi-Unit Scan Body Non-Hex	
				Dentex Scan Body	
Non-Sterile, Mitcon	868113706GFX8	Class IIa	P01020180	Conical Connection Gingiva Former	Intended to use for supporting gingival

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Abutments				<p>Ø5,5 GH2, Ø5,5 GH3, Ø5,5 GH5, Ø5,5 GH7, Ø5,5 GH9, Ø4,5 GH2, Ø4,5 GH3, Ø4,5 GH5, Ø4,5 GH7, Ø4,5 GH9, Ø6,5 GH2, Ø6,5 GH3, Ø6,5 GH5, Ø6,5 GH7, Ø6,5 GH9, Ø7,5 GH2, Ø7,5 GH3, Ø7,5 GH5, Ø7,5 GH7, Ø7,5 GH9, Ø8,5 GH2, Ø8,5 GH3, Ø8,5 GH5, Ø8,5 GH7, Ø8,5 GH9</p> <p>Multi-Unit Gingiva Former</p>	healing on the implant and providing soft tissue contouring by placing them on the corresponding implants.
	868113706TCY9	Class IIa	P01020180	<p>Conical Connection Transfer</p> <p>Open Tray, Closed Tray, Non-Screw</p> <p>Multi-Unit Transfer</p> <p>Open Tray, Closed Tray</p>	To use to take impression of the exact position of the implant in the patient's mouth and the relationship to the rest of the teeth.
	868113706SBY4	Class IIa	P01020180	<p>Scan Body</p> <p>Multi-Unit Scan Body</p> <p>Multi-Unit Scan Body Non-Hex</p>	To be used in digital dentistry to capture accurate digital impressions of patients' oral structures.
Non-Sterile, Kingimplant Abutments	868113706GFX8	Class IIa	P01020180	<p>Conical Connection Gingiva Former</p> <p>Ø5,5 GH2, Ø5,5 GH3, Ø5,5 GH5, Ø5,5 GH7, Ø5,5 GH9, Ø4,5 GH9, Ø4,5 GH2, Ø4,5 GH3, Ø4,5 GH5, Ø4,5 GH7, Ø6,5 GH2, Ø6,5 GH3, Ø6,5 GH5, Ø6,5 GH7, Ø6,5 GH9, Ø7,5 GH2, Ø7,5 GH3, Ø7,5 GH5, Ø7,5 GH7, Ø7,5 GH9, Ø8,5 GH2, Ø8,5 GH3, Ø8,5 GH5, Ø8,5 GH7, Ø8,5 GH9</p> <p>Multi-Unit Gingiva Former</p>	Intended to use for supporting gingival healing on the implant and providing soft tissue contouring by placing them on the corresponding implants
	868113706TCY9	Class IIa	P01020180	<p>Conical Connection Transfer</p> <p>Open Tray, Closed Tray, Non-Screw</p> <p>Multi-Unit Transfer</p> <p>Open Tray, Closed Tray</p>	To use to take impression of the exact position of the implant in the patient's mouth and the relationship to the rest of the teeth..
	868113706SBY4	Class IIa	P01020180	<p>Scan Body</p> <p>Multi-Unit Scan Body</p> <p>Multi-Unit Scan Body Non-Hex</p>	To be used in digital dentistry to capture accurate digital impressions of patients' oral structures.
Non-Sterile, Wizimplant	868113706GFX8	Class IIa	P01020180	Conical Connection Gingiva Former	Intended to use for supporting gingival

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Abutments				Ø5,5 GH2, Ø5,5 GH3, Ø5,5 GH5, Ø5,5 GH7, Ø5,5 GH9, Ø4,5 GH9, Ø4,5 GH2, Ø4,5 GH3, Ø4,5 GH5, Ø4,5 GH7, Ø6,5 GH2, Ø6,5 GH3, Ø6,5 GH5, Ø6,5 GH7, Ø6,5 GH9, Ø7,5 GH2, Ø7,5 GH3, Ø7,5 GH5, Ø7,5 GH7, Ø7,5 GH9, Ø8,5 GH2, Ø8,5 GH3, Ø8,5 GH5, Ø8,5 GH7, Ø8,5 GH9 Multi-Unit Gingiva Former	healing on the implant and providing soft tissue contouring by placing them on the corresponding implants
	868113706TCY9	Class IIa	P01020180	Conical Connection Transfer Open Tray, Closed Tray Long, Non-Screw Multi-Unit Transfer Open Tray, Closed Tray	To use to take impression of the exact position of the implant in the patient's mouth and the relationship to the rest of the teeth.
	868113706SBY4	Class IIa	P01020180	Scan Body Multi-Unit Scan Body Multi-Unit Scan Body Non-Hex	To be used in digital dentistry to capture accurate digital impressions of patients' oral structures.

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 One code is deleted. 868113706ABWE Three codes have been added. 868113706GFX8 868113706TCY9 868113706SBY4 Certificate is changed to from Annex XI Part A template to Annex IX



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