SZUTEST
Konformitätsbewertungsstelle GmbH

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE

According to Annex IX-Chapters I and III of the Regulation (EU) 2017/745 on Medical Devices

Certificate No.: 2975-MED-2501401

Manufacturer:	**DMS DENTAL MEDİKAL SANAYİ VE TİCARET ANONİM ŞİRKETİ** **Main Office**: Oruçreis Mah. Tekstilkent Cad. Tekstilkent B06 Blok No.:10AI, İç Kapı No.:105 Esenler, İstanbul, Türkiye **Assembly-Warehouse**: 600 Evler Mah. 2115 Sokak No.:12/A Bandırma, Balıkesir, Türkiye
Manufacturer's SRN:	TR-MF-000043379
Device Information:	**See Section 2**
Report No.:	MD0060-P001-R01
Specific Conditions or Limitations:	N/A
Revision History:	**See Section 3**

SZUTEST Konformitätsbewertungsstelle GmbH, Notified Body 2975, declares that the aforementioned manufacturer has implemented a quality management system according to Annex IX Chapters I and III of the regulation (EU) 2017/745 on medical devices. This quality system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Regulation. The approved quality system is subject to surveillance pursuant to Annex IX Chapter I Section 3 of the regulation and unannounced site audits.

The Report(s) stated above summarize the conformity assessment results and include references to the relevant CS, harmonized standards, sampled/reviewed technical documentation, and test reports.

SZUTEST Konformitätsbewertungsstelle GmbH must be informed of any substantial changes in the design and/or construction of the device(s). For placing on the market class IIb and class III devices covered by this certificate an EU Technical Documentation Assessment certificate according to Annex IX Chapter II is required.

First Issue Date: 14-01-2025
Revision Date: 15-01-2025
Revision No.: 01
Validity Date: 13-01-2030

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-089

Mehmet IŞIKLAR
General Manager

This certificate can be validated by scanning the QR code or entering necessary information at https://public.szutest-germany.de/

SZUTEST Konformitätsbewertungsstelle GmbH
Friedrich-Ebert-Anlage 36 60325 Frankfurt am Main
www.szutest-germany.de

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Section 2 – Device Information

No	Device(s) / Device Group(s)	Model(s)	Basic UDI-DI	Risk Class
1	Central Dental Compressed Air System	DP 8020-20 2/4 930, DP8020-20 3/6 930, DP 8020-20 4/8 930	8682631666COMPFC	IIa
2	Central Dental Aspiration System	8020-30 DA 6000, 8020-30 DA 9000, 8020-30 DA 12000, 8020-30 DA 15000, 8020-30 DA 18000, 8020-30 DA 20000, 8020-30 DA 25000, 8020-30 DA 30000	8682631666ASPHW	IIa
3	Central Dental Compressed Air and Aspiration System	KOMPAS 8020-40 D-KOMPAS DP2/4-930 & DA10000, 8020-40 D-KOMPAS DP2/4-930 & DA15000, 8020-40 D-KOMPAS DP 4/8 930 & DA30000	8682631666KOMPASS5	IIa

Section 3 – Revision History

Revision No	Revision Date	Identification of changes / definitions
00	14-01-2025	Initial Certification.
01	15-01-2025	Certificate title corrected.

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