



CERTIFICATE

EFESDENTAL MEDİKAL İÇ VE DIŞ TİCARET LİMİTED ŞİRKETİ

KAYIHAN MAH. DOĞRAMACILAR SOK. KARASU APT. NO:10/C
OSMANGAZI / BURSA / TÜRKİYE

*Has been assessed and found to Comply with the Requirements of:
Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:*

ISO 13485:2016

*Medical Devices-Quality Management System is applicable to:
Tıbbi Cihazlar Kalite Yönetim Sistemi*

PRODUCTION, IMPORT, EXPORT, WHOLE PURCHASE AND SALES OF MATERIALS IN THE USE OF DENTISTRY MILLING BURS, DIAMOND DISCS, DENTAL METAL LEVELING DISCS, PORCELAIN AND SKELETON WELDING WIRES, PORCELAIN POLISHING DISCS, DENTAL PLASTERS, DENTAL INVESTMENT MATERIALS, DENTISTRY METAL ALLOYS, DENTAL CRUCIBLES, DENTISTRY OPAQUE, DENTINE, GLAZE LIQUIDS, PORCELAIN SEPARATOR LIQUID, DENTAL PASTES, DENTAL BRUSHES, DENTISTRY MOLDING AND SKELETON WAXES, ALGINATE, SILICONE IMPRESSION MATERIAL, FLASK, DENTAL FLASK SPRING PRESS, GREEN STONE, PINK STONE, PLASTER CUTTING MOTOR, POLISHING MOTOR, MICROMOTOR, ACRYLIC POWDERS, ACRYLIC POWDER LIQUIDS, 3D PRINTER RESINS, TEETH CUTTERS OTHER CONSUMABLES AND DISINFECTANTS USED IN DENTISTRY

DIŞÇİLİKTE KULLANILAN FREZLER, ELMAS DİSKLER, DIŞÇİLİK METAL TESVİYE DİSKLERİ, PORSELEN VE İSKELET KAYNAK TELLERİ, PORSELEN PARLATMA DİSKLERİ, DIŞÇİLİK ALÇILARI, DIŞÇİLİK REVETMANLARI, DIŞÇİLİK METAL ALAŞIMLARI, DIŞÇİLİKTE KULLANILAN POTALAR, DIŞÇİLİK OPAK, DENTİN, GLAZE LİKİTLERİ, PORSELEN AYIRICI LİKİTLERİ, PORSELEN PASTALARI, DENTAL FIRÇALAR, DIŞÇİLİK KALIPLAMA VE İSKELET MUMLARI, ALJİNAT, SİLİKON ÖLÇÜ MATERYALİ, MUFLA, BRİT, YEŞİL TAŞ, PEMBE TAŞ, ALÇI KESME MOTORU, CİLA MOTORU, MİKROMOTOR, AKRİLİK TOZLARI, AKRİLİK TOZU LİKİTİ, 3D PRİNER REÇİNESİ, DIŞ KESİCİLER, DIŞÇİLİKTE KULLANILAN DİĞER SARF MALZEMELERİNİN VE DEZENFEKTANLARIN ÜRETİMİ, İTHALATI, İHRACATI, TOPTAN ALIM VE SATIMI

Certificate Number: 2021/MDQMS/10455
Belge Numarası: 2021/MDQMS/10455

Initial Certification Date: 05.09.2024
İlk Belgelendirme Tarihi: 05.09.2024

Certification Period: 3 Years
Belgelendirme Periyodu: 3 Yıl

Certificate Validity Date: 04.09.2025
Belge Geçerlilik Tarihi: 04.09.2025

IQR Sertifikasyon Onayı



IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.

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**CONFORMITE EUROPEENNE
DECLARATION OF CONFORMITY**

Manufacturer's Name:

Efes Dental Medikal İç ve Dış Ticaret Ltd. Şti.

Manufacturer's Adress:

Kayhan Mh. Dogramacilar Sk. No:10/A
Osmangazi/BURSA Dental

Medical Devices:

Dental Silicone Impression Material, Dental burs and diamond discs, Dental plaster, crown and bridge investment materials, crucibles, polishes, modeling and casting waxes, crown waxes, Dental gels and liquids (varnish, acid, propagation agent), Dental pumice, dental silicone gun, magnetic articulators, Dental light-curing materials, Dental pmma blocks, Dental mics sets, Dental cad cam spreys.

Sterilisation : Non-Sterile

Classification: Class I

Ordinances Applied

- 93/42/EEC Medical Devices Directive

Standards Applied

- EN ISO 13485:2012
- EN ISO 15223-1:2013
- EN ISO 14791:2002
- EN 1041:2011
- EN ISO14155-1:2012
- EN ISO10993-1:2011

Conformity of the products has been assessed in accordance with Annex IX of the Directive. A dossier of technical documentation, as required by the Directive is available. The product listed is designed, manufactured and tested in accordance with the information set out in the dossier.

AUTHORIZED SIGNATORY

Place / Date

Bursa / 01.06.2021

Name Surname

Fatih ALTINEL

Position

General Manager

