



TÜRK STANDARDLARI ENSTİTÜSÜ
TURKISH STANDARDS INSTITUTION

Production Quality Assurance Certificate

Directive 93/42/EEC on Medical devices, Annex V

Notified Body	: Türk Standardları Enstitüsü (TSE) - Necatibey Cad. No:112 Bakanlıklar Ankara Türkiye (NB 1783)
Company Name	: IMICRYL DİŞ MALZEMELERİ SANAYİ VE TİCARET A.Ş.
Company Address	: FETİH MAHALLESİ MAHİR SOKAK NO:5/201 KARATAY KONYA/TURKEY
Manufacturing Site	: FETİH MAHALLESİ MAHİR SOKAK NO:5/201 KARATAY KONYA/TURKEY
Scope	: IMICRYL® DENTAL PROSTHESIS MATERIALS (ACRYLIC TEETH, ISOSIT AND COMPOSITE TEEH, PORCELAIN TEETH, DENTAL ACRYLIC POWDERS, DENTAL ACRYLIC LIQUIDS, PORCELAIN POWDERS AND LIQUIDS), IMICRYL® DENTAL PROTECTIVE MATERIALS (FISSURE SEALANT, FLUORIDE VARNISH, CANAL IRRIGATION AND CLEANING SOLUTION), IMICRYL® DENTAL RESTORATIVE MATERIALS (DENTAL FILLING MATERIALS, DENTAL RESTORATIVE FILLING MATERIALS, DENTAL RESTORATIVE COMPOSITE MATERIALS, DENTAL RESTORATIVE ADHESIVE BONDING MATERIALS, DENTAL CANAL FILLING MATERIALS)
GMDN Code	: 38643, 38644, 16728, 34811, 16187, 31780, 35698, 42345, 16705, 16710, 16709, 36153, 16704, 35875, 38649, 42483, 16182
Classification Rule	: Class IIa, Rule 6 and 8
Inspection Report Number	: 2064-MDD-141/2019-02
First Issue Date	: 24.06.2020
Validity Date	: 26.05.2024

The manufacturer's quality system is inspected in accordance with Annex V of the Medical Device Directive and the quality system meets the requirements of Medical Device Directive Annex V. The Notified Body has the right to carry out the necessary inspections in accordance with Medical Device Directive Annex V Section 4.

Certificate No: 1783- MDD-191



Sezai DOĞAN
Director of Directives
ANKARA Rev00, 24/06/2020

Please check the validity of certificate from TSE's web page "<https://basvuruportal.tse.org.tr/Genel/FirmaArama.aspx?ref=en#open>"

www.tse.org.tr / Necatibey Cad. No: 112 Bakanlıklar - ANKARA / +90 312 416 62 00

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