

EC DECLARATION OF CONFORMITY

AT UYGUNLUK BEYANI

Document Code Dokuman Kodu	Release Date Yayın tarihi	Revision Date Revizyon tarihi	Revision No Revizyon No
DC100007	20.06.2022	10.11.2022	REV00

MANUFACTURER ÜRETİCİ	Öncü Dental Tıbbi Malzeme Sanayi ve Dış Ticaret Anonim Şirketi
HEAD OFFICE MERKEZ OFİS	Molla Gürani Mh. Oğuzhan cd. No:45 Fatih / İSTANBUL
PRODUCTION SITE ÜRETİM YERİ	Akçaburgaz Mah. 9 Yapı San.Sit. 3058 Sk. No:1/33 Esenyurt/İSTANBUL
CONTACT İLETİŞİM	+90 212 621 51 40 / +90 212 523 39 49 / www.oncudental.com
DOCUMENT CODE/REV.DATE/REV.NO DOKUMAN KODU/REV.TARİHİ/REV.NO	DC0001/20.06.2022/REV00
PRODUCT REF CODE & PRODUCT NAME ÜRÜN REF KODU & ÜRÜN ADI	EK-1 Bakınız. /See Annex-1
BASIC UDI TEMEL UDI	8681942658133DD
GMDN CODE & DEFINITION GMDN KODU & AÇIKLAMA	16350 Tray, print, Dental; It is a device specially designed to transport, support and control the material(s) used in printing. 16350 Tepsi, baskı, Dental; Baskı yapımında kullanılan materyal(ler)i taşımak, desteklemek ve kontrol etmek için özel olarak tasarlanmış bir alettir.
CLASSIFICATION RULE & DEFINITION SINIFLANDIRMA KURALI VE AÇIKLAMASI	Class-I Other (without sterile and measuring function) Sınıf-I Diğer (steril ve ölçme fonksiyonu olmayan)
CONFORMITY ASSESSMENT ROUTE UYGUNLUK DEĞERLENDİRME ROTASI	(EU) 2017/745 & Ek IV Uygunluk Beyanı (Ek II & Ek III)
CERTIFICATE APPROVAL DATE & DECLARATION DATE SERTİFİKA GEÇERLİLİK TARİHİ & BEYAN TARİHİ	27.05.2024
APPLIED QUALITY MANAGEMENT SYSTEM UYGULANAN KALİTE YÖNETİM SİSTEMİ	EN ISO 13485:2016
APPLICABLE HARMONIZED STANDARDS UYGULANAN HARMONİZE STANDARTLAR	EN ISO 13485:2016, EN 1041+A1:2013, EN 1641:2009, EN 62366-1/AC:2015, EN 1639:2009, EN 1642:2011, NBOG 2010-1, EN ISO 14971: 2019, EN 1640:2009, EN ISO 15223-1:2016.

EC DECLARATION OF CONFORMITY

AT UYGUNLUK BEYANI

Document Code Dokuman Kodu	Release Date Yayın tarihi	Revision Date Revizyon tarihi	Revision No Revizyon No
DC100007	20.06.2022	10.11.2022	REV00

DECLARATION

AS THE MANUFACTURER, WE DECLARE THAT THE MEDICAL DEVICES WHICH ARE LISTED IN ANNEX-1, MEET THE REQUIREMENTS OF THE 2017/745 MEDICAL DEVICE REGULATIONS AND THE RELEVANT NATIONAL REQUIREMENTS

BEYAN

ÜRETİCİ OLARAK EK-1'DE BELİRTİLEN TIBBİ CİHAZLARIN 2017/745 TIBBİ CİHAZ YÖNETMELİĞİ VE İLGİLİ ULUSAL GEREKLİLİKLERİ KARŞILAŞTIĞINI BEYAN EDERİZ.

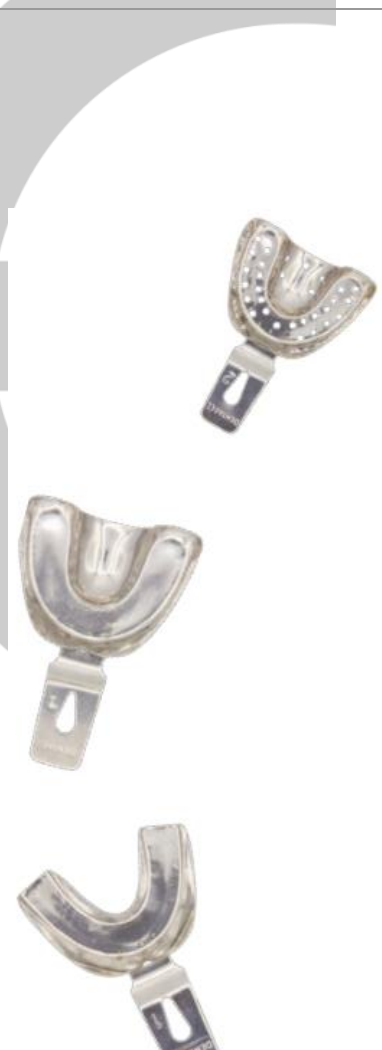
CE MARKING START DATE CE MARKALAMA BAŞLANGIÇ TARİHİ	20.08.2021
PLACE, DATE YER, TARİH	İSTANBUL, TÜRKİYE 20.06.2022
THE LAST VALIDITY DATE OF DECLARATION BELGE GEÇERLİLİK TARİHİ	20.06.2024
SIGNATURED AUTHORIZED İMZA YETKİLİSİ	
PRRC MEVZUAT UYUM SORUMLUSU V.DUYGU MEMİŞ Kalite ve Regülasyon Yöneticisi Quality and Regulatory Affairs Manager	COMPANY OFFICIAL FİRMA YETKİLİSİ ERKAN UÇAR Genel Müdür CEO

EC DECLARATION OF CONFORMITY

AT UYGUNLUK BEYANI

Document Code Dokuman Kodu	Release Date Yayın tarihi	Revision Date Revizyon tarihi	Revision No Revizyon No
DC100007	20.06.2022	10.11.2022	REV00

ANNEX-1 PRODUCT LIST EK-1 ÜRÜN LİSTESİ

REF # REF #	Product Name Ürün Adı	Barcode No Barkod No	Product Picture Ürün Görseli
DC1000ANT2A	IMPRESSION TRAY ANATOMICAL NO 2 LOWER	8681942655491	
DC1000DLI1A	IMPRESSION TRAY PERFORETED NO 1 LOWER	8681942655507	
DC1000DLI1U	IMPRESSION TRAY PERFORETED NO 1 UPPER	8681942655514	
DC1000DLI2A	IMPRESSION TRAY PERFORETED NO 2 LOWER	8681942655521	
DC1000DLI2U	IMPRESSION TRAY PERFORETED NO 2 UPPER	8681942655538	
DC1000DLI3A	IMPRESSION TRAY PERFORETED NO 3 LOWER	8681942655545	
DC1000DLI3U	IMPRESSION TRAY PERFORETED NO 3 UPPER	8681942655552	
DC1000DONER	IMPRESSION TRAY HALF	8681062148057	
DC1000DSS1A	IMPRESSION TRAY UNPERFORETED NO 1 LOWER	8681942655569	
DC1000DSS1U	IMPRESSION TRAY UNPERFORETED NO 1 UPPER	8681942655576	
DC1000DSS2A	IMPRESION TRAY UNPERFORETED NO 2 LOWER	8681942655583	
DC1000DSS2U	IMPRESSION TRAY UNPERFORETED NO 2 UPPER	8681942655590	
DC1000DSS3A	IMPRESSION TRAY UNPERFORETED NO 3 LOWER	8681942655606	

EC DECLARATION OF CONFORMITY

AT UYGUNLUK BEYANI

Document Code Dokuman Kodu	Release Date Yayın tarihi	Revision Date Revizyon tarihi	Revision No Revizyon No
DC100007	20.06.2022	10.11.2022	REV00

DC1000DSS3U	IMPRESSION TRAY UNPERFORETED NO 3 UPPER	8681942655613	
DC1000DSZ1A	IMPRESSION TRAY UNPERFORETED NO 1 LOWER	8681942655620	
DC1000DSZ1U	IMPRESSION TRAY UNPERFORETED NO 1 UPPER	8681942655637	
DC1000DSZ2A	IMPRESSION TRAY UNPERFORETED NO 2 LOWER	8681942655644	
DC1000DSZ2U	IMPRESSION TRAY UNPERFORETED NO 2 UPPER	8681942655651	
DC1000DSZ3A	IMPRESSION TRAY UNPERFORETED NO 3 LOWER	8681942655668	
DC1000DSZ3U	IMPRESSION TRAY UNPERFORETED NO 3 UPPER	8681942655675	
DC1000KND2A	IMPRESSION TRAY KENEDY NO 2 LOWER	8681942600408	
DC1000KND2U	IMPRESSION TRAY KENEDY NO 2 UPPER	8681942600392	
DC1000KND3A	IMPRESSION TRAY KENEDY NO 3 LOWER	8681942600415	
DC1000KND3U	IMPRESSION TRAY KENEDY NO 3 UPPER	8681942600422	