

**BELGE NO / DOCUMENT NO:** RTA.UB.842

**İMALATÇI/ MANUFACTURER:**

RTA LABORATUVARLARI BİYOLOJİK ÜRÜNLER İLAÇ VE MAKİNE SAN. TİC. A.Ş.  
GEPOSB CUMHURİYET CADDESİ NO:3 GEBZE / KOCAELİ / TURKEY

**ÜRÜN TANIMI / PRODUCT DESCRIPTION:**

Ekteki ürün listesine bakınız.  
*See attached product list*

**ÜRÜN TİPİ / PRODUCT TYPE:**

98/79/AT VÜCUT DIŞINDA KULLANILAN (İN VİTRO) TIBBİ TANI CİHAZLARI YÖNETMELİĞİ  
EK III ÜRÜNÜ

*98/79/EC IN VITRO DIAGNOSTIC MEDICAL DEVICES DIRECTIVE ANNEX III PRODUCT*

**UYGUNLUK DEĞERLENDİRME PROSEDÜRÜ / CONFORMITY ASSESMENT PROCEDURE:**  
YUKARIDA TANIMLANAN ÜRÜN, 98/79/AT NUMARALI AB DİREKTİFİNİN BİRİNCİ EKİNDE  
YER ALAN TEMEL GEREKLİLİKLER DAHİL OLMAK ÜZERE TÜM İLGİLİ  
GEREKLİLİKLERİNE VE İLGİLİ HARMONİZE STANDARTLARIN GEREKLERİNE UYGUNDUR.

*WE HEREBY DECLARE THAT THE DESIGNATED PRODUCTS CONFORM TO ALL APPLICABLE  
REQUIREMENTS OF THE COUNCIL DIRECTIVE 98/79/EC PROVISION INCLUDING THE  
ESSENTIAL REQUIREMENTS GIVEN ON ANNEX I AND ALL APPLICABLE HARMONISED  
STANDARDS.*

**ÜRÜN SINIFI / PRODUCT CLASSIFICATION:**

GENEL IVD CİHAZLAR (IVD DİĞER) / *GENERAL IVD DEVICES*

BU YÖNETMELİĞE UYGUNLUK İLE İLGİLİ AÇIKLAMALAR VE BİLGİLER ÜRÜN TEKNİK  
DOSYASINDA BELİRTİLMİŞTİR.

*THE JUSTIFICATION FOR COMPLIANCE WITH THIS DIRECTIVE IS GIVEN ON THE PRODUCT  
TECHNICAL FILE.*

**TANZİM EDEN / DECLARED BY:**

ORÇUN KALKAN – GENEL MÜDÜR / GENERAL MANAGER  
RTA LABORATUVARLARI BİYOLOJİK ÜRÜNLER İLAÇ VE MAKİNE SAN. TİC. A.Ş.

**YETKİLİ İMZA / AUTHORISED SIGNATURE:**



**YER – TARİH / PLACE – DATE:** KOCAELİ- 17.04.2020



## AB- UYGUNLUK BEYANI EC – DECLARATION of CONFORMITY

### Ek-1 Ürün Listesi/ Annex-1 Product List

Birincil Ürün Numarası <i>Barcode Number</i>	Marka Adı <i>Brand</i>	Ürün Katalog Numarası <i>Product Catalog No</i>	Ürün Adı <i>Product Name</i>
8698918031814	RTA	04006	LJ MEDIUM (16*110 MM CAM TÜP)
8698918031821	RTA	04007	LJ MEDIUM (17*115 MM POLİKARBONAT TÜP)
8698918031838	RTA	04008	LJ MEDIUM w/o GLYCERIN (17*115 MM POLİKARBONAT TÜP)
8698918033481	RTA	04009	COLETSOS MEDIUM
8698918033498	RTA	04010	LOWENSTEİN JENSEN- İZONİYAZİT 1UG/ML
8698918033504	RTA	04011	LOWENSTEİN JENSEN-OFLOKSASİN 8 UG/ML
8698918033511	RTA	04012	LOWENSTEİN JENSEN-İZONİYAZİT 0,2 UG/ML
8698918033528	RTA	04013	LOWENSTEİN JENSEN- STREPTOMİSİN 4 UG/ML
8698918033535	RTA	04014	LOWENSTEİN JENSEN- RİFAMPİSİN 40 UG/ML
8698918033542	RTA	04015	LOWENSTEİN JENSEN- ETAMBUTOL 2 UG/ML
8698918033559	RTA	04016	LOWENSTEİN JENSEN- PAS 0,5 UG/ML
8698918032583	RTA	04017	LOWENSTEİN JENSEN- TCH 2 UG/ML
8698918032576	RTA	04018	LOWENSTEİN JENSEN- PNB 500 UG/ML
8698918033566	RTA	04019	LOWENSTEİN JENSEN- GLİSEROL
8698918034495	RTA	04020	LJ MEDIUM w/OFLOXACIN 40 UG/ML
8698918034594	RTA	04021	LJ MEDIUM w/ETHIONAMIDE 20 UG/ML
8698918034600	RTA	04022	LJ MEDIUM w/CAPREOMYCIN 20 UG/ML
8698918034617	RTA	04023	LJ MEDIUM w/KANAMYCIN 20 UG/ML
8698918034839	RTA	04024	LJ MEDIUM w/D.CYCLOSERİN 30 UG/ML
8698918035836	RTA	04025	LOWENSTEİN JENSEN- ETİONAMİD 40 UG/ML
8698918035843	RTA	04026	LOWENSTEİN JENSEN- AMİKASİN 40 UG/ML
8698918035850	RTA	04027	LOWENSTEİN JENSEN- KANAMİSİN 30 UG/ML
8698918035867	RTA	04028	LOWENSTEİN JENSEN- OFLOKSASİN 2 UG/ML
8698918037939	RTA	04029	LJ MEDIUM w/ MOXIFLOXACIN 8 UG/ML
8698918040144	RTA	04031	LJ MEDIUM w/AMİKACIN 30 UG/ML
8684000440800	RTA	04032	LJ MEDIUM w/CAPREOMYCIN 40 UG/ML
8698918040137	RTA	04033	LJ MEDIUM w/LEVOFLOXACIN 2 UG/ML
8684000440886	RTA	04034	LJ MEDIUM w/MOXIFLOXACIN 1 UG/ML
8684000441470	RTA	04035	LJ MEDIUM w/MOXIFLOXACIN 0.25 UG/ML
8684000441487	RTA	04036	LJ MEDIUM w/PAS 1 UG/ML