



THE REPUBLIC OF TÜRKİYE
MINISTRY OF HEALTH
MEDICINES AND MEDICAL DEVICES AGENCY OF TÜRKİYE

Certificate No: 368129

Date of Issue : 3 October 2023

CERTIFICATE OF FREE SALE

To whom it may concern,

It is hereby certified that the products detailed in the attached schedule, which are manufactured by "BİOTA DİAGNOSTİK SAĞLIK HİZMETLERİ SANAYİ VE TİCARET LİMİTED ŞİRKETİ" (Atatürk Mh. Kerembey Sk. No:3/3 ATAŞEHİR İSTANBUL), have been affixed with the CE mark in accordance with Medical Device Directives of the European Union (EU) and are freely sold in Türkiye and EU.

This certificate is issued to be given to the relevant competent authorities of "Russian Federation" and is valid for 36 months from the date of issue.

Yours sincerely,

Ömer Faruk KURU
Head of Medical Devices
Registration and Coordination Department

This certificate consists of 2 page/s and 16 products. The products listed in the attached schedule are registered from the date of issuance of this certificate and information about the current status of these products is accessible through



<https://utsuygulama.saglik.gov.tr/UTS/vatandas#/vatTibbiCihazListele>.

Address: Söğütözü Mahallesi, 2176. Sokak No:5 06520 Çankaya/ANKARA
Phone: +90 312 218 30 00 Fax: +90 312 218 34 60 <https://www.titck.gov.tr>

Date of Issue : 3 October 2023

PRODUCT SCHEDULE

#	Barkod	Brand	Label Name	Reference No / Version / Model	GMDN Code
1	8684308520020	BIOTA	VABIO360 Automatic Blood Count Analyzer	VABIO360	35476
2	8684308520037	BIOTA	VABIO580 Automatic Blood Count Analyzer	VABIO580	35476
3	8684308520044	BIOTA	VABIO360 Plus Automatic Blood Count Analyzer	VABIO360+	35476
4	8684308520051	BIOTA	VABIO360 Diluent (20l)	VA-360D	58237
5	8684308520068	BIOTA	VABIO360 Lyse (500 ml)	VA-360L	17123
6	8684308520075	BIOTA	VABIO360 Cleanser (50 ml)	VA-360C	17123
7	8684308520082	BIOTA	VABIO580 Diluent (20 L)	VA-580D	58237
8	8684308520099	BIOTA	VABIO580 L1 Lyse (500 ML)	VA-580L1	17123
9	8684308520105	BIOTA	VABIO580 L2 Lyse (1L)	VA-580L2	17123
10	8684308520112	BIOTA	VABIO580 LH Lyse (500 ML)	VA-580LH	17123
11	8684308520129	BIOTA	VABIO580 Cleanser (50 ml)	VA-580C	17123
12	8684308520136	BIOTA	SABIO140 Automatic Sedimentation Analyzer	SABIO140	56691
13	8684308520143	BIOTA	SABIO JR Automatic Sedimentation Analyzer	SABIO JR	56691
14	8684308520150	SABIO	ESR TEST CARD (1000 TESTS)	SA-TD1000	56691
15	8684308520167	SABIO	ESR TEST CARD (5000 TESTS)	SA-TD5000	56691
16	8684308520174	SABIO	ESR TEST CARD (10000 TESTS)	SA-TD10000	56691

End of product schedule





THE REPUBLIC OF TÜRKİYE
MINISTRY OF HEALTH
MEDICINES AND MEDICAL DEVICES AGENCY OF TÜRKİYE

Certificate No: 368309

Date of Issue : 3 October 2023

CERTIFICATE OF FREE SALE

To whom it may concern,

It is hereby certified that the products detailed in the attached schedule, which are manufactured by "BIOTA DIAGNOSTİK SAĞLIK HİZMETLERİ SANAYİ VE TİCARET LİMİTED ŞİRKETİ" (Atatürk Mh. Kerembey Sk. No:3/3 ATAŞEHİR İSTANBUL), have been affixed with the CE mark in accordance with Medical Device Directives of the European Union (EU) and are freely sold in Türkiye and EU.

This certificate is issued to be given to the relevant competent authorities of "Romania" and is valid for 36 months from the date of issue.

Yours sincerely,

Ömer Faruk KURU

Head of Medical Devices

Registration and Coordination Department

This certificate consists of 3 page/s and 16 products. The products listed in the attached schedule are registered from the date of issuance of this certificate and information about the current status of these products is accessible through



<https://utsuygulama.saglik.gov.tr/UTS/vatandas#/vatTibbiCihazListele>.

Address: Söğütözü Mahallesi, 2176. Sokak No:5 06520 Çankaya/ANKARA

Phone: +90 312 218 30 00 Fax: +90 312 218 34 60 <https://www.titck.gov.tr>

Date of Issue : 3 October 2023

PRODUCT SCHEDULE

#	Barkod	Brand	Label Name	Reference No / Version / Model	GMDN Code
1	8684308520020	BIOTA	VABIO360 Automatic Blood Count Analyzer	VABIO360	35476
2	8684308520037	BIOTA	VABIO580 Automatic Blood Count Analyzer	VABIO580	35476
3	8684308520044	BIOTA	VABIO360 Plus Automatic Blood Count Analyzer	VABIO360+	35476
4	8684308520051	BIOTA	VABIO360 Diluent (20l)	VA-360D	58237
5	8684308520068	BIOTA	VABIO360 Lyse (500 ml)	VA-360L	17123
6	8684308520075	BIOTA	VABIO360 Cleanser (50 ml)	VA-360C	17123
7	8684308520082	BIOTA	VABIO580 Diluent (20 L)	VA-580D	58237
8	8684308520099	BIOTA	VABIO580 L1 Lyse (500 ML)	VA-580L1	17123
9	8684308520105	BIOTA	VABIO580 L2 Lyse (1L)	VA-580L2	17123
10	8684308520112	BIOTA	VABIO580 LH Lyse (500 ML)	VA-580LH	17123
11	8684308520129	BIOTA	VABIO580 Cleanser (50 ml)	VA-580C	17123
12	8684308520136	BIOTA	SABIO140 Automatic Sedimentation Analyzer	SABIO140	56691
13	8684308520143	BIOTA	SABIO JR Automatic Sedimentation Analyzer	SABIO JR	56691
14	8684308520150	SABIO	ESR TEST CARD (1000 TESTS)	SA-TD1000	56691
15	8684308520167	SABIO	ESR TEST CARD (5000 TESTS)	SA-TD5000	56691



Date of Issue : 3 October 2023

16	8684308520174	SABIO	ESR TEST CARD (10000 TESTS)	SA-TD10000	56691
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End of product schedule





CERTIFICATE

BİOTA DİAGNOSTİK SAĞLIK HİZMETLERİ SANAYİ VE TİCARET LİMİTED ŞİRKETİ

ATATÜRK MAH. KEREMBAY SOK. MUZİPO KIDS BLOK NO:3/3
ATAŞEHİR / İSTANBUL / 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:*

**DESING, MANUFACTURE AND SALES OF IVD MEDICAL
DEVICES AND CONSUMABLES**

**IVD MEDİKAL CİHAZ VE SARF MALZEMELERİNİN
TASARIMI, ÜRETİMİ VE SATIŞI**

Certificate Number: 2023/MDQMS/11077
Belge Numarası: 2023/MDQMS/11077

Initial Certification Date: 14.06.2023
İlk Belgelendirme Tarihi: 14.06.2023

Certification Period: 3 Years
Belgelendirme Periyodu: 3 Yıl

Certificate Validity Date: 13.06.2025
Belge Geçerlilik Tarihi: 13.06.2025

IQR Sertifikasyon Onayı



IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.

Beşevler Mah. Kocayunus Sk. No:3 Arslan Han Plaza K:2 Nilüfer / BURSA
Tel.: +90.224.266 00 16 Faks: +90.224.249 41 13 www.iqrcert.com e-posta: info@iqrcert.com

DECLARATION OF CONFORMITY

BIOTA DIAGNOSTIK SAĞLIK HİZMETLERİ SAN. VE TIC. LTD. STİ.

Address : Ataturk Mah. Kerembey Sok.
No:3/3, 34758-Atasehir
Istanbul/Turkey
Phone : +90 212 2485264
E-mail : info@biotadiagnostik.com

We hereby declare that the below mentioned products meet provisions of the Council Regulation (EU) 2017/746 In vitro Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Description Of The Product : ESR Analyser
Product Brand : SABIO
Product Type/Model : SABIO140 Automated ESR Analyser (Running directly from EDTA samples) and SABIO140 Test Cards (SA-TD1000, SA-TD5000, SA-TD10000)
Classification : Class A, according to Annex VIII of IVD (EU) 2017/746

General Applicable Directives

In vitro Diagnostic Directive council regulations (EU) 2017/746 concerning in vitro diagnostic instruments

Standards

All applicable harmonized standards published in the official journal of the European Communities:
EN13612:2002; EN ISO 13485, EN 61010-1:20010; EN61010-2-101:2002; EN61326-1:2013; EN61326-2-6:2013; EN62304:2008; EN62366:2008; EN13640:2002

Date Of Issue : 20.06.2019

Signature :

BIOTA DIAGNOSTIK SAĞLIK
HİZ. SAN. VE TIC. LTD. STİ.
Ataturk Mah. Kerembey Sok.No.3/3
Atasehir - Istanbul
Kozysagı V.D. 722 049 1247

Name : Erdal Güntürkün
Position : CEO