POLISH CENTRE FOR
TESTING AND CERTIFICATION
www.pcbc.gov.pl

BM.433.0024.2020/KW/MV/2024/0499 Warsaw, 04.09.2024

Digitally signed by Bolea Petru
Date: 2025.05.15 19:12:48 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

To Whom It May Concern

The Polish Centre for Testing and Certification (PCBC) hereby confirms that before the expiry of the validity of the **EC Certificates No. 1434-IVDD-506/2021, 1434-IVDD-507/2021, 1434-IVDD-505/2021, 1434-IVDD-499/2021, 1434-IVDD-500/2021, 1434-IVDD-501/2021, 1434-IVDD-502/2021, 1434-IVDD-497/2021, 1434-IVDD-498/2021, 1434-IVDD-236/2022 end 1434-IVDD-237/2022** issued for the in vitro diagnostic medical devices whose manufacturer is Anatolia Tanı ve Biyoteknoloji Ürünleri Araştırma Geliştirme Sanayi ve Ticaret A.Ş., an agreement for the conformity assessment in accordance with *Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices* in respect of the devices covered by the expired certificates, was signed with **Notified Body 2962**.

Therefore, pursuant to Art. 2 of the *Regulation (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 13 June 2024 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards a gradual roll-out of Eudamed, the obligation to inform in case of interruption or discontinuation of supply, and transitional provisions for certain in vitro diagnostic medical devices*, the **EC Certificates No. 1434-IVDD-506/2021, 1434-IVDD-507/2021, 1434-IVDD-505/2021, 1434-IVDD-499/2021, 1434-IVDD-500/2021, 1434-IVDD-501/2021, 1434-IVDD-502/2021, 1434-IVDD-497/2021, 1434-IVDD-498/2021, 1434-IVDD-236/2022 end 1434-IVDD-237/2022 remain valid.**

Polish Centre for Testing and Certification remains responsible for the appropriate surveillance in respect of the applicable requirements relating to the devices covered by the certificate mentioned above.

Sincerely,

Izabela Czeluśniak

Deputy Head of Medical Device
Certification Department

QMD Services
Quality | Medical | Devices

BECAUSE PATIENT SAFETY MATTERS.

QMD Services GmbH
Zelinkagasse 10/3
1010 Wien Austria

www.qmdservices.com

Notified Body according to Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Notified Body identification no.: 2962

EU Quality Management System Certificate

REGULATION (EU) 2017/746, Annex IX Chapter I and III

Manufacturer:

Anatolia Tanı ve Biyoteknoloji Ürünleri Araştırma Geliştirme Sanayi ve Ticaret A.Ş.

Hasanpaşa Mah. Beydağı Sok. No: 1-9H
34920 Sultanbeyli / İstanbul
Türkiye
Single Registration Number: TR-MF-000022487

Site 2:
Anatolia Tanı ve Biyoteknoloji Ürünleri Araştırma Geliştirme Sanayi ve Ticaret Anonim Şirketi İstanbul Endüstri ve Ticaret Serbest Bölge Şubesi
Aydınlı SB Mah. Matraş Cad. No: 18/Z02
34953 Tuzla / İstanbul
Türkiye

Certificate ID: IQMS/00001/0 v002

Issue date: 17. December 2024
Valid from: 27. May 2024
Expiry date: 26. May 2029
Report No.: 1751-1297-105

The Notified Body QMD Services GmbH declares that the requirements of Annex IX, Chapter I and III of the Regulation (EU) 2017/746 have been met for the listed products. The assessment has proven that the manufacturer has established and applies a Quality Management System which is subject to periodic surveillance as required for the applicable conformity assessment in accordance to Regulation (EU) 2017/746. For the placing on the market of Class D devices, and self-test, near patient test and companion diagnostic devices an Annex IX Chapter II certificate is required.

For and on behalf of QMD Services GmbH, a Notified Body for the above mentioned regulation:

Anni Koubek
CEO

Florian Heffeter
CEO

a8140cd3-6e90-4017-baf6-69c420a63f55

QMD Services GmbH
Zelinkagasse 10/3
1010 Wien Austria

www.qmdservices.com

Notified Body according to Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Notified Body identification no.: 2962

Products

Certificate ID: IQMS/00001/0 v002

Issue date: 17. December 2024
Valid from: 27. May 2024
Expiry date: 26. May 2029
Report No.: 1751-1297-105

Class C

Generic device group(s) (EMDN code 3rd level & IVP code)	**Intended purpose(s)**
W0105 - infectious diseases IVP 3011 - In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)	IVR 0503 - Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents IVR 0504 - Devices intended to be used to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging

The validity of this certification depends on conditions and/or is limited to the following: -none-

5f13a216-b2a4-4ee9-bf9b-e9364697f6df

QMD Services GmbH
Zelinkagasse 10/3
1010 Wien Austria

www.qmdservices.com

Notified Body according to Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Notified Body identification no.: 2962

Certificate History

Certificate ID: IQMS/00001/0 v002

Issue date: 17. December 2024
Valid from: 27. May 2024
Expiry date: 26. May 2029

Version	Description	Issue Date
001	Initial certification 1612-1297-101	27. May 2024
002	Scope extension 1751-1297-105 for additional 3 class C products and addition of IVR 0504	17. December 2024

8ab2bab6-04e7-480e-bb05-121df5ce580d

ODPIS

CERTIFICATE

EC Certificate No. 1434-IVDD-236/2022

Full Quality Assurance System
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Anatolia Tanı ve Biyoteknoloji Ürünleri Araştırma Geliştirme Sanayi ve Ticaret A.Ş. Hasanpaşa Mah. Beydağı Sok. No:1-9H Sultanbeyli, İstanbul, Turkey

for the design, manufacture and final inspection of *in vitro* diagnostic medical device
List A

Bosphore HDV Quantification- Detection Kit v1

complies with requirements
of Annex IV (excluding Section 4, 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 25.05.2022 to 16.05.2025

The date of issue of the Certificate: 25.05.2022

The date of the first issue of the Certificate: 16.05.2012

CE 1434

Issued under the Contract No. MD-24/2020
Application No: 024/2020c
Certificate bears the authorized person signature.
Warsaw, 25/05/2022
Module H7

Tomasz Koeber

Tomasz Koeber
Director of Medical Devices
Certification Department

Kancelaria Notarialna Jacek Kossewki Anna Kulka
Spółka Partnerska
00-897 Warszawa, aleja Solidarności 119/125 lok. 79
tel.: 22 812 91 38 / 22 812 09 78

Repertorium A Nr 3664 **/2022**
Dnia 14 CZE. 2022

Ja, **Jacek Kossewski** notariusz w Warszawie poświadczam za zgodność tego odpisu sporządzonego w Kancelarii Notarialnej przy Alei Solidarności nr 119/125 lok. 79 z okazanym dokumentem. ----------

Pobrano: a/ taksy notarialnej 6,00 zł na podst. §13 pkt 2 Rozporządzenia Ministra Sprawiedliwości z 28.06.2004 r. w sprawie maksymalnych stawek taksy notarialnej (Dz. U. z 2018 roku, poz. 272, ze zm.) -----

b/ podatku VAT 23% 1,38 zł na podstawie art. 5 ust. 1 pkt 1 ustawy z 11.03.2004 r. o podatku od towarów i usług (Dz. U. z 2017 roku, poz. 1221 ze zm.). ----------

JACEK KOSSEWSKI NOTARIUSZ W WARSZAWIE

Jacek Kossewski
notariusz

Niniejszym poświadczam autentyczność podpisu **Jacka Kossewskiego** – notariusza i pieczęci urzędowej notariusza **Jacka Kossewskiego**
ę skarbową w kwocie 26,00 zł
a 15 czerwca 2022 r.

Sędzia WSO
ds. cywilnych
ydzia Sądu Okręgowego w Warszawie
Renata Drozd-Sweklej
oby uwierzytelniającej i jej tytuł służbowy)

va)

APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. Państwo / *Country*: **Rzeczpospolita Polska**
Niniejszy dokument urzędowy / *This public document*
2. podpisany został przez **Renata Drozd-Sweklej**
has been signed by
3. działającego w charakterze
acting in the capacity of **Prezes**
4. zaopatrzony jest w pieczęć/stempel
bears the seal/stamp of **Sąd Okręgowy w Warszawie**

Poświadczony / *Certified*
5. w / *at* Warszawa 6. dnia / *the* **2022-06-24**
7. przez / *by* Ministerstwo Spraw Zagranicznych
8. Nr / *N°* **33643/2022**
9. Pieczęć/stempel
Seal/stamp:
10. Podpis:
Signature:
Tomasz Wasilewski
Referat ds. Legalizacji
DEPARTAMENT KONSULARNY

MINISTERSTWO SPRAW ZAGRANICZNYCH

Kancelaria Notarialna Jacek Kossewki Anna Kulka
Spółka Partnerska
00-897 Warszawa, aleja Solidarności 119/125 lok. 79
tel.: 22 812 91 38 / 22 812 09 78

Repertorium A Nr 3664 **/2022**
Dnia 14 CZE. 2022

Ja, **Jacek Kossewski** notariusz w Warszawie poświadczam za zgodność tego odpisu sporządzonego w Kancelarii Notarialnej przy Alei Solidarności nr 119/125 lok. 79 z okazanym dokumentem. ----------

Pobrano: a/ taksy notarialnej 6,00 zł na podst. §13 pkt 2 Rozporządzenia Ministra Sprawiedliwości z 28.06.2004 r. w sprawie maksymalnych stawek taksy notarialnej (Dz. U. z 2018 roku, poz. 272, ze zm.) -----

b/ podatku VAT 23% 1,38 zł na podstawie art. 5 ust. 1 pkt 1 ustawy z 11.03.2004 r. o podatku od towarów i usług (Dz. U. z 2017 roku, poz. 1221 ze zm.). ----------

JACEK KOSSEWSKI NOTARIUSZ W WARSZAWIE

Jacek Kossewski
notariusz

Niniejszym poświadczam autentyczność podpisu **Jacka Kossewskiego** – notariusza i pieczęci urzędowej notariusza **Jacka Kossewskiego**
Pobrano opłatę skarbową w kwocie 26,00 zł
Warszawa, dnia 15 czerwca 2022 r.

SĄD OKRĘGOWY W WARSZAWIE XII

Sędzia WSO
ds. cywilnych
Sędzia Sądu Okręgowego w Warszawie
Renata Droza-Sweklej
(podpis osoby uwierzytelniającej i jej tytuł służbowy)

(pieczęć urzędowa)

MINISTERSTWO SP

ODPIS

CERTIFICATE

EC Certificate No. 1434-IVDD-237/2022

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Anatolia Tanı ve Biyoteknoloji Ürünleri Araştırma Geliştirme Sanayi ve Ticaret A.Ş.
Hasanpaşa Mah. Beydağı Sok. No:1-9H
Sultanbeyli, İstanbul, Turkey

i.e. *in vitro* diagnostic medical devices
List A

Bosphore HDV Quantification- Detection Kit v1

in terms of design documentation, comply with requirements
of Annex IV (Section 4) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 25.05.2022 to 16.05.2025

The date of issue of the Certificate: 25.05.2022

The date of the first issue of the Certificate: 16.05.2012

CE 1434

Issued under the Contract No. MD-24/2020
Application No: 024/2020c
Certificate bears the authorized person signature.
Warsaw, 25/05/2022
Module H6/V1

Tomasz Koeber

Tomasz Koeber
Director of Medical Devices
Certification Department

Kancelaria Notarialna Jacek Kossewki Anna Kulka
Spółka Partnerska
00-897 Warszawa, aleja Solidarności 119/125 lok. 79
tel.: 22 812 91 38 / 22 812 09 78

Repertorium A Nr 3665 **/2022**
Dnia 14 CZE. 2022

Ja, **Jacek Kossewski** notariusz w Warszawie poświadczam za zgodność tego odpisu sporządzonego w Kancelarii Notarialnej przy Alei Solidarności nr 119/125 lok. 79 z okazanym dokumentem. ----------

Pobrano: a/ taksy notarialnej 6,00 zł na podst. §13 pkt 2 Rozporządzenia Ministra Sprawiedliwości z 28.06.2004 r. w sprawie maksymalnych stawek taksy notarialnej (Dz. U. z 2018 roku, poz. 272, ze zm.) -----

b/ podatku VAT 23% 1,38 zł na podstawie art. 5 ust. 1 pkt 1 ustawy z 11.03.2004 r. o podatku od towarów i usług (Dz. U. z 2017 roku, poz. 1221 ze zm.). ----------

Jacek Kossewski
notariusz

Niniejszym poświadczam autentyczność podpisu
…ssewskiego – notariusza i pieczęci
…ej notariusza **Jacka Kossewskiego**
opłatę skarbową w kwocie 26,00 zł
…a, dnia 15 czerwca 2022 r.

Sędzia Sądu Okręgowego
ds. cywilnych
Sędzia Sądu Okręgowego w Warszawie
Renata Drozd-Sweklej
(podpis osoby uwierzytelniającej i jej tytuł służbowy)

…ędowa)

APOSTILLE
(Convention de La Haye du 5 octobre 1961)

1. Państwo / *Country*: **Rzeczpospolita Polska**
Niniejszy dokument urzędowy / *This public document*
2. podpisany został przez **Renata Drozd-Sweklej**
has been signed by
3. działającego w charakterze
acting in the capacity of **Prezes**
4. zaopatrzony jest w pieczęć/stempel
bears the seal/stamp of **Sąd Okręgowy w Warszawie**

Poświadczony / *Certified*
5. w / *at* Warszawa 6. dnia / *the* **2022-06-24**
7. przez / by Ministerstwo Spraw Zagranicznych
8. Nr / *N°* **33642/2022** 10. Podpis:
9. Pieczęć/stempel *Signature:*
Seal/stamp:

Tomasz Wasilewski
Referat ds. Legalizacji
DEPARTAMENT KONSULARNY

MINISTERSTWO SPRAW ZAGRANICZNYCH

Kancelaria Notarialna Jacek Kossewki Anna Kulka
Spółka Partnerska
00-897 Warszawa, aleja Solidarności 119/125 lok. 79
tel.: 22 812 91 38 / 22 812 09 78

Repertorium A Nr 3665 **/2022**

Dnia 14 CZE. 2022

Ja, **Jacek Kossewski** notariusz w Warszawie poświadczam za zgodność tego odpisu sporządzonego w Kancelarii Notarialnej przy Alei Solidarności nr 119/125 lok. 79 z okazanym dokumentem. ----------

Pobrano: a/ taksy notarialnej 6,00 zł na podst. §13 pkt 2 Rozporządzenia Ministra Sprawiedliwości z 28.06.2004 r. w sprawie maksymalnych stawek taksy notarialnej (Dz. U. z 2018 roku, poz. 272, ze zm.) -----

b/ podatku VAT 23% 1,38 zł na podstawie art. 5 ust. 1 pkt 1 ustawy z 11.03.2004 r. o podatku od towarów i usług (Dz. U. z 2017 roku, poz. 1221 ze zm.). ----------

JACEK KOSSEWSKI NOTARIUSZ W WARSZAWIE

Jacek Kossewski
notariusz

Niniejszym poświadczam autentyczność podpisu **Jacka Kossewskiego** – notariusza i pieczęci urzędowej notariusza **Jacka Kossewskiego**
Pobrano opłatę skarbową w kwocie 26,00 zł
Warszawa, dnia 15 czerwca 2022 r.

Sędzia Wydziału ds. cywilnych
Sędzia Sądu Okręgowego w Warszawie
Renata Drozd-Sweklej
(podpis osoby uwierzytelniającej i jej tytuł służbowy)

SĄD OKRĘGOWY W WARSZAWIE

(pieczęć urzędowa)

MINISTERSTWO SPRAWIEDLIWOŚCI

CERTIFICATE

EC Certificate No. 1434-IVDD-497/2021

Full Quality Assurance System
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Anatolia Tanı ve Biyoteknoloji Ürünleri Araştırma Geliştirme Sanayi ve Ticaret A.Ş.
Hasanpaşa Mah. Beydağı Sok. No:1-9H Sultanbeyli, İstanbul, Turkey

for the design, manufacture and final inspection of *in vitro* diagnostic medical device
List A

Bosphore HCV Quantification Kit

complies with requirements
of Annex IV (excluding Section 4, 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 17.12.2021 to 29.12.2023

The date of issue of the Certificate: 17.12.2021

The date of the first issue of the Certificate: 30.12.2010

CE 1434

Issued under the Contract No. **MD-21/2018**
Application No: 034/2018-02
Certificate bears the qualified signature.
Warsaw, date next to signature
Module H7

Director Medical Devices Certification Department

CERTIFICATE

EC Certificate No. 1434-IVDD-498/2021

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Anatolia Tanı ve Biyoteknoloji Ürünleri Araştırma Geliştirme Sanayi ve Ticaret A.Ş.
Hasanpaşa Mah. Beydağı Sok. No:1-9H Sultanbeyli, İstanbul, Turkey

i.e. *in vitro* diagnostic medical devices
List A

Bosphore HCV Quantification Kit

in terms of design documentation, comply with requirements
of Annex IV (Section 4) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 17.12.2021 to 29.12.2023
The date of issue of the Certificate: 17.12.2021

The date of the first issue of the Certificate: 30.12.2010

CE 1434

Issued under the Contract No. **MD-21/2018**
Application No: 034/2018-02
Certificate bears the qualified signature.
Warsaw, date next to signature
Module H6/V1

Director Medical Devices Certification Department

CERTIFICATE

EC Certificate No. 1434-IVDD-501/2021

Full Quality Assurance System
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Anatolia Tanı ve Biyoteknoloji Ürünleri Araştırma Geliştirme Sanayi ve Ticaret A.Ş.
Hasanpaşa Mah. Beydağı Sok. No:1-9H Sultanbeyli, İstanbul, Turkey

for the design, manufacture and final inspection of *in vitro* diagnostic medical device
List A

Bosphore HBV Quantification Kit

complies with requirements
of Annex IV (excluding Section 4, 6) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 17.12.2021 to 29.12.2023

The date of issue of the Certificate: 17.12.2021

The date of the first issue of the Certificate: 30.12.2010

CE 1434

Issued under the Contract No. **MD-21/2018**
Application No: 033/2018-02
Certificate bears the qualified signature.
Warsaw, date next to signature
Module H7

Director Medical Devices Certification Department

CERTIFICATE

EC Certificate No. 1434-IVDD-502/2021

EC Design-examination
Directive 98/79/EC concerning
***in vitro* diagnostic medical devices**

Polish Centre for Testing and Certification certifies
that manufactured by:

Anatolia Tanı ve Biyoteknoloji Ürünleri Araştırma Geliştirme Sanayi ve Ticaret A.Ş.
Hasanpaşa Mah. Beydağı Sok. No:1-9H Sultanbeyli, İstanbul, Turkey

i.e. *in vitro* diagnostic medical devices
List A

Bosphore HBV Quantification Kit

in terms of design documentation, comply with requirements
of Annex IV (Section 4) to Directive 98/79/EC (as amended)
implemented into Polish law,
as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 17.12.2021 to 29.12.2023
The date of issue of the Certificate: 17.12.2021

The date of the first issue of the Certificate: 30.12.2010

CE 1434

Issued under the Contract No. **MD-21/2018**
Application No: 033/2018-02
Certificate bears the qualified signature.
Warsaw, date next to signature
Module H6/V1

Director Medical Devices Certification Department

QMD Services GmbH
Headquarters
Zelinkagasse 10/3
1010 Vienna, Austria
Tel.: +43 1 53 30 077
Operations Office
Am Winterhafen 1
4020 Linz, Austria
E-Mail: office@qmdservices.com
Website: www.qmdservices.com

Anatolia Tanı ve Biyoteknoloji Ürünleri Araştırma Geliştirme Sanayi ve Ticaret A.Ş.
Mr. Elif Akyüz
Hasanpaşa Mah. Beydağı Sok.
No: 1-9H Sultanbeyli
34920 Istanbul
Turkey

03. October 2024

Notified Body Confirmation Letter

Reference: 1830-1297-114

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2024/1860 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, QMD Services, a Notified Body (NB) designated against Regulation (EU) 2017/746 (IVDR) and identified by the number 2962 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of IVDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of IVDR with the following manufacturer:

Anatolia Tanı ve Biyoteknoloji Ürünleri Araştırma Geliştirme Sanayi ve Ticaret A.Ş.
Hasanpaşa Mah. Beydağı Sok.
No: 1-9H Sultanbeyli
34920 Istanbul
Turkey

SRN Number (if available): TR-MF-000022487

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an IVDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the Directive 98/79/EC. Table 2 identifies the devices for which an IVDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the Directive 98/79/EC.

In the case of devices covered by certificates issued under Directive Directive 98/79/EC (IVDD) that expired after 26 May 2022 and before 09 July 2024, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under IVDR by the date of IVDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 54 of IVDR or Article 92 of the IVDR respectively, by the 09 July 2024 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 110.3c of IVDR (as amended by (EU) 2024/1860), are shown below:

- 31 December 2027 for devices covered by an IVDD certificate regardless of their risk class under the IVDR
- For devices not requiring the involvement of a notified body under the IVDD, but requiring it under the IVDR and for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with Directive 98/79/EC, the following dates apply:
    - 31 December 2027, for class D devices;
    - 31 December 2028, for class C devices;
    - 31 December 2029, for class B devices and for class A devices placed on the market in sterile condition

On behalf of the Notified Body,

ppa Ingrid Blaimauer

Head of operations

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under Directive 98/79/EC:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD/ Certificate Reference(s) of the devices under IVDR application, and the NB Identification
N/A	N/A	N/A	N/A

Table 2: Devices covered by this letter and for which the NB is <u>NOT yet</u> responsible for appropriate surveillance of the corresponding devices under Directive 98/79/EC:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
Bosphore HIV-1 Quantification Kit	Class D	Identification of the corresponding device under IVDD	1434-IVDD-499/2021 1434-IVDD-500/2021 Issued by Polish Centre for Testing and Certification – (NB 1434)
Bosphore HBV Quantification Kit	Class D	Identification of the corresponding device under IVDD	1434-IVDD-501/2021 1434-IVDD-502/2021 Issued by Polish Centre for Testing and Certification – (NB 1434)
Bosphore HCV Quantification Kit	Class D	Identification of the corresponding device under IVDD	1434-IVDD-497/2021 1434-IVDD-498/2021 Issued by Polish Centre for Testing and Certification – (NB 1434)
Bosphore HDV Quantification-Detection Kit v1	Class D	Identification of the corresponding device under IVDD	1434-IVDD-236/2022 1434-IVDD-237/2022 Issued by Polish Centre for Testing and Certification – (NB 1434)
Bosphore Atypical CAP Panel Kit	Class C	Identification of the corresponding device under IVDD	1434-IVDD-506/2021 Issued by Polish Centre for Testing and Certification – (NB 1434)
Bosphore Viral Infections in the ImmunosuppressedPanel Kit	Class C	Identification of the corresponding device under IVDD	1434-IVDD-507/2021 Issued by Polish Centre for Testing and Certification – (NB 1434)
Bosphore CMV Quantification Kit	Class C	Identification of the corresponding device under IVDD	1434-IVDD-505/2021 Issued by Polish Centre for Testing and

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
			Certification – (NB 1434)

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-10-03	1830-1297-114	Initial issue / Decision based on signed contract dated 13.04.2023.

EC-DECLARATION OF CONFORMITY / EC-UYGUNLUK BEYANI

Document No: DOC251v4

ACCORDING TO THE 98/79/EC DIRECTIVE ANNEX 3/
98/79/EC DİREKTİFİ EK 3 UYARINCA;

MANUFACTURER/ ÜRETİCİ:

Anatolia Tanı ve Biyoteknoloji Ürünleri Ar-Ge San. ve Tic. A.Ş.

Hasanpaşa Mah. Beydağı Sk. No: 1-9 H, 34920 Sultanbeyli, Istanbul TURKEY

PRODUCT DESIGNATION/ÜRÜNLERİN TANIMI:

Bosphore HCV Genotyping Kit v1, Bosphore HCV Genotyping Kit v3
Bosphore HCV Genotyping Kit v5, Bosphore HCV Genotyping Kit v7
Bosphore HCV Genotype 3 Genotyping Kit v1

PRODUCT CLASS/ÜRÜN SINIFI:

IVD Other (Not Included in Annex II List)/ IVD Diğer (Ek II Liste Dışı)

We herewith declare that the above mentioned product meets the provisions of the directive 98/79/EC for in vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer./ Yukarıda belirtilen ürünlerin 98/79/EC Vücut Dışında Kullanılan Tıbbi Tanı Cihazları Direktifi'nin şartlarına uygun olduğunu beyan ederiz. İlgili tüm dokümantasyon üretici tarafından saklanmaktadır.

LOCATION-DATE/YER-TARİH: **ISTANBUL, 21 JAN 2022/ 21.01.2022**

LEGALLY BINDING SIGNATURE/YETKİLİ İMZA:

ANATOLİA TANI VE BİYOTEKNOLOJİ ÜRÜNLERİ
AR-GE SANAYİ VE TİCARET ANONİM ŞİRKETİ
Hasanpaşa Mah. Beydağı Sokak No:1-9H
34920 Sultanbeyli/İST. Tic.Sic.No:738589
Mersis No: 0068 0797 5830 0025
Tel: 0216 330 04 55 Faks: 0216 330 00 56
SULTANBEYLİ V.D.: 068 079 7583

Dr. Elif Akyüz, R&D Director/Ar-Ge Direktörü

Anatolia Tanı A.Ş.; considers the following regulations and standards: / aşağıdaki mevzuat ve standartları uygulamaktadır:

◊ Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices/ Avrupa Parlamentosu ve 27 Ekim 1998 tarihli konseyi'nin 98/79/EC Vücut Dışında Kullanılan Tıbbi Tanı Cihazları Direktifi

◊ The Harmonized Standard "EN ISO 13485:2016 Medical Devices–Quality Management Systems–Requirements For Regulatory Purposes"/ "EN ISO 13485:2016 Tıbbi Cihazlar-Kalite yönetim sistemleri-Mevzuat Amaçları Bakımından Şartlar" uyumlaştırılmış standardı

◊ The Harmonized Standard "EN ISO 14971:2020 - Application of the Risk Management to Medical Devices"/ "EN ISO 14971:2020 Risk Yönetiminin Tıbbi Cihazlara Uygulanması" uyumlaştırılmış standardı

EC-DECLARATION OF CONFORMITY / EC-UYGUNLUK BEYANI

Document No: DOC252v9

ACCORDING TO THE 98/79/EC DIRECTIVE ANNEX 3/
98/79/EC DİREKTİFİ EK 3 UYARINCA;

MANUFACTURER/ ÜRETİCİ:

Anatolia Tanı ve Biyoteknoloji Ürünleri Ar-Ge San. ve Tic. A.Ş.

Hasanpaşa Mah. Beydağı Sk. No: 1-9 H, 34920 Sultanbeyli, Istanbul TURKEY

PRODUCT DESIGNATION/ÜRÜNLERİN TANIMI:

Bosphore HPV Screening Kit v1
Bosphore HPV Screening Kit v2
Bosphore HPV Screening Kit v3
Bosphore HPV Genotyping High Risk Basic Kit v1
Bosphore HPV Genotyping High Risk Kit v1
Bosphore HPV Genotyping High Risk Kit v2
Bosphore HPV HR-LR-Genotyping Kit v1
Bosphore HPV HR-LR-Genotyping Kit v2
Bosphore HPV HR-LR-Genotyping Kit v3

PRODUCT CLASS/ÜRÜN SINIFI:

IVD Other (Not Included in Annex II List)/ IVD Diğer (Ek II Liste Dışı)

We herewith declare that the above mentioned product meets the provisions of the directive 98/79/EC for in vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer./ Yukarıda belirtilen ürünlerin 98/79/EC Vücut Dışında Kullanılan Tıbbi Tanı Cihazları Direktifi'nin şartlarına uygun olduğunu beyan ederiz. İlgili tüm dokümantasyon üretici tarafından saklanmaktadır.

LOCATION-DATE/YER-TARİH: **ISTANBUL, 13 MAY 2022/ 13.05.2022**

LEGALLY BINDING SIGNATURE/YETKİLİ İMZA:

CE

ANATOLİA TANI VE BİYOTEKNOLOJİ ÜRÜNLERİ AR-GE SANAYİ VE TİCARET ANONİM ŞİRKETİ
Hasanpaşa Mah. Beydağı Sokak No:1-9H
34920 Sultanbeyli/İST. Tic.Sic.No:738589
Mersis No: 0068 0797 5830 0025
Tel: 0216 330 04 55 Faks: 0216 330 0044
SULTANBEYLİ V.D: 068 079 7583

Dr. Elif Akyüz, R&D Director/Ar-Ge Direktörü

Anatolia Tanı A.Ş.; considers the following regulations and standards: / aşağıdaki mevzuat ve standartları uygulamaktadır:

◊ Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices/ Avrupa Parlamentosu ve 27 Ekim 1998 tarihli konseyi'nin 98/79/EC Vücut Dışında Kullanılan Tıbbi Tanı Cihazları Direktifi

◊ The Harmonized Standard "EN ISO 13485:2016 Medical Devices–Quality Management Systems–Requirements For Regulatory Purposes"/ "EN ISO 13485:2016 Tıbbi Cihazlar-Kalite yönetim sistemleri-Mevzuat Amaçları Bakımından Şartlar" uyumlaştırılmış standardı

◊ The Harmonized Standard "EN ISO 14971:2019 - Application of the Risk Management to Medical Devices"/ "EN ISO 14971:2019 Risk Yönetiminin Tıbbi Cihazlara Uygulanması" uyumlaştırılmış standardı

EC-DECLARATION OF CONFORMITY / EC-UYGUNLUK BEYANI

Document No/Doküman No: DOC294v4

ACCORDING TO THE 98/79/EC DIRECTIVE ANNEX 4/
98/79/EC DİREKTİFİ EK 4 UYARINCA;

MANUFACTURER/ ÜRETİCİ:

Anatolia Tanı ve Biyoteknoloji Ürünleri Ar-Ge San. ve Tic. A.Ş.

Hasanpaşa Mah. Beydağı Sk. No: 1-9 H, 34920 Sultanbeyli, Istanbul TURKEY

PRODUCT DESIGNATION/ ÜRÜNLERİN TANIMI:

Bosphore HBV Quantification Kit

RELATED CERTIFICATE NUMBERS/ İLGİLİ SERTİFİKA NUMARALARI:

EC Design-Examination No/ EC Tasarım-İnceleme Sertifika No: 1434-IVDD-502/2021
EC Certificate No (Full Quality Assurance System)/
EC Sertifika No (Tam Kalite Yönetim Sistemi): 1434-IVDD-501/2021

EC NOTIFIED BODY AND CODE/ EC ONAYLANMIŞ KURULUŞ VE KODU:

Polish Centre for Testing and Certification-1434

PRODUCT CLASS/ÜRÜN SINIFI:

Annex II List A/ Ek II Liste A

We herewith declare that the above-mentioned product meets the provisions of the directive 98/79/EC for in vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer./ Yukarıda belirtilen ürünlerin 98/79/EC Vücut Dışında Kullanılan Tıbbi Tanı Cihazları Direktifi'nin şartlarına uygun olduğunu beyan ederiz. İlgili tüm dokümantasyon üretici tarafından saklanmaktadır.

LOCATION-DATE/YER-TARİH: **ISTANBUL, 17 DEC 2021/ 17.12.2021**

LEGALLY BINDING SIGNATURE/YETKİLİ İMZA:

CE 1434

ANATOLİA TANI VE BİYOTEKNOLOJİ ÜRÜNLERİ
AR-GE SANAYİ VE TİCARET ANONİM ŞİRKETİ
Hasanpaşa Mah. Beydağı Sokak No:1-9H
34920 Sultanbeyli/İST. Tic.Sic.No:738589
Mersis No: 0068 0797 5830 0025
Tel: 0216 330 04 55 Fax: 0216 330 04 54
SULTANBEYLİ V.D.: 068 079 7583

Dr. Elif Akyüz, R&D Director / Ar-ge Direktörü

Anatolia Tanı A.Ş.; considers the following regulations and standards: / aşağıdaki mevzuat ve standartları uygulamaktadır:

◊ Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices/ Avrupa Parlamentosu ve 27 Ekim 1998 tarihli konseyi'nin 98/79/EC Vücut Dışında Kullanılan Tıbbi Tanı Cihazları Direktifi

◊ The Harmonized Standard "EN ISO 13485:2016 Medical Devices–Quality Management Systems–Requirements For Regulatory Purposes"/ " EN ISO 13485:2016 Tıbbi Cihazlar-Kalite yönetim sistemleri-Mevzuat Amaçları Bakımından Şartlar" uyumlaştırılmış standardı

◊ The Harmonized Standard "EN ISO 14971:2012 - Application of the Risk Management to Medical Devices"/ "EN ISO 14971:2012 Risk Yönetiminin Tıbbi Cihazlara Uygulanması" uyumlaştırılmış standardı

EC-DECLARATION OF CONFORMITY / EC-UYGUNLUK BEYANI

Document No/Doküman No: DOC295v4

ACCORDING TO THE 98/79/EC DIRECTIVE ANNEX 4/
98/79/EC DİREKTİFİ EK 4 UYARINCA;

MANUFACTURER/ ÜRETİCİ:

Anatolia Tanı ve Biyoteknoloji Ürünleri Ar-Ge San. ve Tic. A.Ş.

Hasanpaşa Mah. Beydağı Sk. No: 1-9 H, 34920 Sultanbeyli, Istanbul TURKEY

PRODUCT DESIGNATION/ ÜRÜNLERİN TANIMI:

Bosphore HCV Quantification Kit

RELATED CERTIFICATE NUMBERS/ İLGİLİ SERTİFİKA NUMARALARI:

EC Design-Examination No/ EC Tasarım-İnceleme Sertifika No: 1434-IVDD-498/2021
EC Certificate No (Full Quality Assurance System)/
EC Sertifika No (Tam Kalite Yönetim Sistemi): 1434-IVDD-497/2021

EC NOTIFIED BODY AND CODE/ EC ONAYLANMIŞ KURULUŞ VE KODU:

Polish Centre for Testing and Certification-1434

PRODUCT CLASS/ÜRÜN SINIFI:

Annex II List A/ Ek II Liste A

We herewith declare that the above-mentioned product meets the provisions of the directive 98/79/EC for in vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer./ Yukarıda belirtilen ürünlerin 98/79/EC Vücut Dışında Kullanılan Tıbbi Tanı Cihazları Direktifi'nin şartlarına uygun olduğunu beyan ederiz. İlgili tüm dokümantasyon üretici tarafından saklanmaktadır.

LOCATION-DATE/YER-TARİH: **ISTANBUL, 17 DEC 2021/ 17.12.2021**

LEGALLY BINDING SIGNATURE/YETKİLİ İMZA:

CE 1434

ANATOLIA TANI VE BİYOTEKNOLOJİ ÜRÜNLERİ
AR-GE SANAYİ VE TİCARET ANONİM ŞİRKETİ
Hasanpaşa Mah. Beydağı Sokak No:1-9H
34920 Sultanbeyli/IST. Tic.Sic.No:738589
Mersis No: 0068 0797 5830 0025
Tel: 0216 330 04 55 Faks: 0216 [illegible]
SULTANBEYLİ V.D: 068 079 7583

Dr. Elif Akyüz, R&D Director / Ar-ge Direktörü

Anatolia Tanı A.Ş.; considers the following regulations and standards: / aşağıdaki mevzuat ve standartları uygulamaktadır:

◊ Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices/ Avrupa Parlamentosu ve 27 Ekim 1998 tarihli konseyi'nin 98/79/EC Vücut Dışında Kullanılan Tıbbi Tanı Cihazları Direktifi

◊ The Harmonized Standard "EN ISO 13485:2016 Medical Devices–Quality Management Systems–Requirements For Regulatory Purposes"/ " EN ISO 13485:2016 Tıbbi Cihazlar-Kalite yönetim sistemleri-Mevzuat Amaçları Bakımından Şartlar" uyumlaştırılmış standardı

◊ The Harmonized Standard "EN ISO 14971:2012 - Application of the Risk Management to Medical Devices"/ "EN ISO 14971:2012 Risk Yönetiminin Tıbbi Cihazlara Uygulanması" uyumlaştırılmış standardı

EC-DECLARATION OF CONFORMITY / EC-UYGUNLUK BEYANI

Document No/Doküman No: DOC302v5

ACCORDING TO THE 98/79/EC DIRECTIVE ANNEX 4/
98/79/EC DİREKTİFİ EK 4 UYARINCA;

MANUFACTURER/ ÜRETİCİ:

Anatolia Tanı ve Biyoteknoloji Ürünleri Ar-Ge San. ve Tic. A.Ş.
Hasanpaşa Mah. Beydağı Sk. No: 1-9 H, 34920 Sultanbeyli, Istanbul TURKEY

PRODUCT DESIGNATION/ ÜRÜNLERİN TANIMI:

Bosphore HDV Quantification Detection Kit v1

RELATED CERTIFICATE NUMBERS/ İLGİLİ SERTİFİKA NUMARALARI:

EC Design-Examination No/ EC Tasarım-İnceleme Sertifika No: 1434-IVDD-237/2021
EC Certificate No (Full Quality Assurance System)/
EC Sertifika No (Tam Kalite Yönetim Sistemi): 1434-IVDD-236/2021

EC NOTIFIED BODY AND CODE/ EC ONAYLANMIŞ KURULUŞ VE KODU:

Polish Centre for Testing and Certification-1434

PRODUCT CLASS/ÜRÜN SINIFI:

Annex II List A/ Ek II Liste A

We herewith declare that the above-mentioned product meets the provisions of the directive 98/79/EC for in vitro diagnostic medical devices. All supporting documentation is retained under the premises of the manufacturer./ Yukarıda belirtilen ürünlerin 98/79/EC Vücut Dışında Kullanılan Tıbbi Tanı Cihazları Direktifi'nin şartlarına uygun olduğunu beyan ederiz. İlgili tüm dokümantasyon üretici tarafından saklanmaktadır.

LOCATION-DATE/YER-TARİH: **ISTANBUL, 25 MAY 2022/ 25.05.2022**

LEGALLY BINDING SIGNATURE/YETKİLİ İMZA:

CE 1434

ANATOLİA TANI VE BİYOTEKNOLOJİ ÜRÜNLERİ
AR-GE SANAYİ VE TİCARET ANONİM ŞİRKETİ
Hasanpaşa Mah. Beydağı Sokak No:1-9H
34920 Sultanbeyli/İST. Tic.Sic.No:738589
Mersis No: 0068 0797 5830 0025
Tel: 0216 330 04 55 Faks: 0216 330 04 54
SULTANBEYLİ V.D: 068 079 7583

Dr. Elif Akyüz, R&D Director / Ar-Ge Direktörü

Anatolia Tanı A.Ş.; considers the following regulations and standards: / aşağıdaki mevzuat ve standartları uygulamaktadır:

◊ Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices/ Avrupa Parlamentosu ve 27 Ekim 1998 tarihli konseyi'nin 98/79/EC Vücut Dışında Kullanılan Tıbbi Tanı Cihazları Direktifi

◊ The Harmonized Standard "EN ISO 13485:2016 Medical Devices–Quality Management Systems–Requirements For Regulatory Purposes"/ "EN ISO 13485:2016 Tıbbi Cihazlar-Kalite yönetim sistemleri-Mevzuat Amaçları Bakımından Şartlar" uyumlaştırılmış standardı

◊ The Harmonized Standard "EN ISO 14971:2019 - Application of the Risk Management to Medical Devices"/ "EN ISO 14971:2019 Risk Yönetiminin Tıbbi Cihazlara Uygulanması" uyumlaştırılmış standardı

EC-DECLARATION OF CONFORMITY

Document No: DOC 1008v2

Manufacturer	: Anatolia Tanı ve Biyoteknoloji Ürünleri Ar-Ge San. ve Tic. A.Ş.
Address	: Hasanpaşa Mah. Beydağı Sk No:1-9 H, 34920 Sultanbeyli, Istanbul, TURKEY
SRN	: TR-MF-000022487
Authorized Representative	: Not Applicable
Product Name	: Bosphore Viral DNA/RNA Extraction Spin Kit
Basic UDI-DI	: 868001894EXKSPNVR10002ZP
Product Code	: ABXDR1
Product Class	: Regulation 2017/746/EU, Annex IV, Self-Declared, Non-Sterile Class A
Notified Body Details	: Not Applicable
Intended Use	: Bosphore Viral DNA/RNA Extraction Spin Kit has been designed for manual extraction of nucleic acids from biological samples including blood, serum, plasma, sputum, saliva, cerebrospinal fluid, amniotic fluid, liquid-based cytology, bone marrow, cell culture, urine, semen, breast milk, swab, bronchoalveolar lavage, buffy coat, mouthwash, tissue, tears and stool samples.
GMDN Code	: 52521

This declaration of conformity is issued under the sole responsibility of Anatolia Tanı ve Biyoteknoloji Ürünleri Ar-Ge San. ve Tic. A.Ş. We hereby declare that the medical device(s) specified above meet the provisions of the Regulation 2017/746/EU Directive on *in vitro diagnostic* medical devices. This declaration is supported by the Quality System approval to EN ISO 13485 issued by the notified body. All supporting documentation is retained under the premises of the manufacturer.

EN ISO 13485 Issued By	: Polish Centre for Testing and Certification ul. Pulawska 469, 02-844 Warsaw, Poland
Location-Date	: ISTANBUL, 26 May 2022
Legal Signature	**:** Dr. Elif Akyüz, R&D Director

ANATOLİA TANI VE BİYOTEKNOLOJİ ÜRÜNLERİ AR-GE SANAYİ VE TİCARET ANONİM ŞİRKETİ
Hasanpaşa Mah. Beydağı Sokak No:1-9H
34920 Sultanbeyli/IST. Tic.Sic.No:738589
Mersis No: 0068 0797 5630 0005
Tel: 0216 330 04 55 Fax: 0216 [illegible]
SULTANBEYLİ V.D. 060 [illegible]

Anatolia Tanı ve Biyoteknoloji Ürünleri Ar-Ge San. ve Tic. A.Ş. considers the following regulations and standards:

◊ Regulation (EU) 2017/746 of The European Parliament and of The Council of 5 April 2017 on *in vitro diagnostic* medical devices

◊ The Harmonized Standard "EN ISO 13485:2016 Medical Devices–Quality Management Systems–Requirements for Regulatory Purposes"

◊ The Harmonized Standard "EN ISO 14971:2019 - Application of the Risk Management to Medical Devices"