



CERTIFICATE

EC Certificate No. 1434-IVDD-486/2021

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

Polish Centre for Testing and Certification certifies
that manufactured by:

**Novatech Tıbbi Cihaz Ürünleri Sanayi ve Ticaret A.Ş.
2.Organize Sanayi Bölgesi Hacı Sani Konukoğlu Bulvarı 83228 Nolu
Sokak No: 17 Sehitkamil / Gaziantep, Turkey**

in vitro diagnostic medical devices
for self-testing

**NOVACHECK® Early Pregnancy Test
STARCHECK® Early Pregnancy Test**

in terms of design documentation, comply with requirements
of Annex III (Section 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 11.11.2021 to 27.05.2024

The date of issue of the Certificate: 10.11.2021

The date of the first issue of the Certificate: 23.09.2021



Issued under the Contract No. MD-04/2021
Application No: 374a/2020
Certificate bears the qualified signature.
Warsaw, 10/11/2021
Module A1
FBM-30-E_10

Anna
Małgorzata
Wyroba

Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2021.11.10
16:18:41 +01'00'

Vice-President



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

BM.433.0374.2020/KW/MV/2023/0123

Warsaw, 14.03.2024

**Novatech Tıbbi Cihaz Ürünleri
Sanayi ve Ticaret A.Ş.
2.Organize Sanayi Bölgesi
Hacı Sani Konukoğlu Bulvarı
83228 Nolu Sokak No: 17
Sehitkamil / Gaziantep, Turkey**

Pursuant the application for change dated February 26th, 2024, Polish Centre for Testing and Certification kindly informs that assessment of documentation regarding Early Pregnancy Test is accomplished. Change related to additional brand name Vedexa® is accepted.

Implementation of the change does not represent a significant change in design or intended purpose under Regulation (EU) 2017/746 Article 110(3) and the related IVDD Certificate no. 1434-IVDD-486/2021 remains valid until 27.05.2024.

Yours Sincerely,

Anna Zofia
Żuk-Wasek

Elektronicznie podpisany
przez Anna Zofia Żuk-Wasek
Data: 2024.03.14 07:47:12
+01'00'

**Manager
In Vitro Diagnostic
Medical Device
Certification Division**



CERTIFICATION.
TESTING.
TRAINING.

Polish Centre for Testing and Certification
469 Puławska Street, 02-844 Warsaw
Tel.: +48 22 46 45 200
pcbc@pcbc.gov.pl

NIP 9512063356
REGON 015276609
KRS 0000144813

Initial capital
16.000.000 PLN
(fully paid)

Bank account: Bank Pekao S.A.
nr 90 1240 6003 1111 0000 4946 7594

The company registered in the District Court for
the Capital City of Warsaw, XIIIth Commercial Division



BM.433.0374.2020/KW/MV/2024/0120

Warsaw, 14.03.2024

To Whom It May Concern,

Polish Centre for Testing and Certification informs about the change to **EC Certificate No. 1434-IVDD-486/2021** issued for Novatech Tıbbi Cihaz Ürünleri Sanayi ve Ticaret A.Ş.

The list of brands covered by the certificate has been updated:

NOVACHECK® Early Pregnancy Test RF100C

NOVACHECK® Pregnancy (HCG) Rapid Test RF100D

STARCHECK® Early Pregnancy Test RF100C

STARCHECK® Pregnancy (HCG) Rapid Test RF100D

Valfast® Early Pregnancy Test RF100C

Valfast® Pregnancy (HCG) Rapid Test RF100D

Mimea® Early Pregnancy Test RF100C

Mimea® Pregnancy (HCG) Rapid Test RF100D

Vedexa® Early Pregnancy Test RF100C

Vedexa® Pregnancy (HCG) Rapid Test RF100D

Implementation of the change does not represent a significant change in design or intended purpose under Regulation (EU) 2017/746 Article 110(3) and the related IVDD Certificate no. 1434-IVDD-486/2021 issued 11.11.2021 remains valid until 27.05.2024.

Yours Sincerely,

Tomasz Koeber Elektronicznie podpisany
przez Tomasz Artur Koeber
Data: 2024.03.14 11:39:45
+01'00'

**Head of Medical Device
Certification Department**

