MD – 2020, or. Chişinău,
srt. Calea Orheiului 111/5
tel. 406 - 299; 406 – 282,
tel./fax. 406 – 271
GSM 069140864
www.becor.md

МД 2020, г.Кишинэу ,
ул. Калеа Орхеюлуй 111/5
тел. 406 - 299;406 - 282
факс. 406 - 271
GSM 069140864
www.becor.md

Nr :**206/23**
Data :**19.10.2023**

Catre: CENTRUL PENTRU ACHIZITII PUBLICE CENTRALIZATE IN SANATATE
(MD-2009, Republica Moldova, Chişinău str. Cosmescu 3**)**

În atenţia : **Comisiei de evaluare a ofertelor la procedura de** achiziția Testelor pentru tehnologia de examinare de laborator a donatorilor de sânge/componente sanguine și sângelui/componentelor sanguine donat la prima etapă de triere și la a doua etapă de triere, întru realizarea Programului Național „Securitatea transfuzională şi autoasigurarea ţării cu produse sanguine” conform necesităților pentru anul 2024 prin procedura de achiziție licitatie deschisa Nr: ocds-b3wdp1-MD-1695305626407 din data de 24.10.2023

DECLARAŢIE PE PROPRIA RASPUNDERE

Noi, IM „Becor”SRL confirmam veridicitatea datelor in actele prezentate

Ofertant/candidat

. . . . . .

(semnătura autorizată)

Digitally signed by Lazari Cristina
Date: 2023.10.20 11:49:52 EEST
Reason: MoldSign Signature
Location: Moldova

Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. ..... din .....

Solicitantul IM „BECOR" SRL, cu sediul str. Calea Orheiului 111/5, MD-2020, Chisinau, Republica Moldova, tel./fax: (+373) 022 406 282, e-mail becordtm@gmail.com, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea şi punerea la dispoziţie pe piaţă a:

1. Teste de laborator cobas MPX 09040862190;
2. Teste de laborator cobas MPX Control Kit 09040846190;

Se anexează următoarele acte:

1. Scrisoare de autorizare Roche Diagnostics GmbH - IM Becor SRL;
2. Declaraţii de conformitate CE, Roche Diagnostics GmbH (1declaratie);
3. EC Design-Examination Certificate CE 708021;
4. EC Certificate-Full Quality Assurance CE 707974.

Data 25.09.2023 Semnătura _____

Tabelul de recepţionare a notificării
(se completează de către Agenţie în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepţionării notificării, inclusiv motivul refuzului	Accept
Data/nr. de ordine atribuit notificării de către Agenţie (în cazul acceptării recepţionării)	Nr. 7613 din 03.10.2023
Numele, prenumele, funcţia persoanei responsabile de recepţionarea dosarului	Ceslat Marin biolingvinar
Semnătura persoanei responsabile	Ceslat

Declaration of Conformity

as per Annex IV of the Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 via BSI as the Notified Body (registration no. BSI-NL 2797)

Document No.:	**DOC-2022-11**
Manufacturer:	**Roche Molecular Systems, Inc.** **1080 US Highway 202 South** **Branchburg, NJ 08876** **USA**
Authorized Representative:	**Roche Diagnostics GmbH** **Sandhofer Strasse 116** **68305 Mannheim** **Germany**
Name, Address and Identification number of the Notified Body:	**BSI Group The Netherlands B.V.** **Notified Body Number: 2797** **Say Building, John M. Keynesplein 9, 1066 EP** **Amsterdam, Netherlands**

Roche Molecular Systems, Inc. declares that the *in vitro* diagnostic medical device:

Product Name:	**cobas®** MPX *For use on the* ***cobas®*** *5800/6800/8800 Systems*
P/N:	09040862190: **cobas®** MPX – 480 09040846190: **cobas®** MPX Control Kit

Description:
The **cobas®** MPX test,for use on **cobas®** 5800/6800/8800 Systems is a qualitative *in vitro* test for the direct detection of Human Immunodeficiency Virus Type 1 (HIV-1) Group M RNA, HIV-1 Group O RNA, Human Immunodeficiency Virus Type 2 (HIV-2) RNA, Hepatitis C Virus (HCV) RNA, and Hepatitis B Virus (HBV) DNA in human plasma and serum.

The complete Intended Use is contained in the **cobas®** MPX Package Insert.

Complies with the requirements of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

This declaration is supported by the following certificates:
EC Certificate – Full Quality Assurance: CE 707974, first issued 2019-03-26, valid until 2025-05-26
EC Design-Examination Certificate: CE 708021, first issued 2019-03-26, valid until 2025-05-26

For presentation to the Authorities of Republic of Moldova

16th of May 2019

Letter of Authorization

The undersigned company

Roche Diagnostics Polska sp. z o.o., with its registered office in Warsaw at Bobrowiecka 8 Street, 00-728 Warsaw, entered into the Register of Entrepreneurs kept by the District Court for the Capital City of Warsaw, XIII Commercial Division of the National Court Register under registration number (KRS) 0000132695, tax identification number (NIP): 527-23-22-068, share capital PLN 8 000 000

hereby confirms that

IM "BECOR" SRL,
111/5 Calea Orheiului str., MD-2020, Chisinau, Republic of Moldova

being sole distributor of Roche Diagnostics Products on the territory of the Republic of Moldova is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova, and to perform Essential duties required by Moldovan regulations regarding medical devices.

This Letter of Authorization is valid until revocation by a notice in writing.

Wojciech Szymanik
Proxy
Roche Diagnostics Polska Sp. z o.o.
Bobrowiecka 8 str.
00-728 Warsaw, Poland

Michał Wrzos
Proxy
Roche Diagnostics Polska Sp. z o.o.
Bobrowiecka 8 str.
00-728 Warsaw, Poland

REPUBLICA MOLDOVA, mun. CHISINAU IDNO 1003600060828 I.M. «BECOR» S.R.L. CU RASPUNDERE LIMITATA

Declaration of Conformity

as per Annex IV of the Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 via BSI as the Notified Body (registration no. BSI-NL 2797)

Document No.: **DOC-2022-11**

The Manufacturer agrees to develop, implement, and maintain a documented post-production monitoring process, including the notification of reportable events, under the European Medical Device Vigilance System Guidelines. As a legal manufacturer, Roche Molecular Systems, Inc., is solely responsible for the product. This declaration is issued under the sole responsibility of Roche Molecular Systems, Inc.

Place: Tucson, AZ

Date: 19-May-2022

Jeff Boone

Jeff Boone
Vice President, Quality Management

Place: Pleasanton, CA

Date: 17-May-2022

Rita Hoady

Rita Hoady
Network Lead Molecular Lab
Director, Global Regulatory Affairs