

<u>הנדון</u>

שם התכשיר: <u>Tecentrig®</u>מספר הרישום: <u>158-66-34982-00/01</u>

אני הרוקח/ת הממונה <u>לילי אדר</u> של בעל הרישום <u>רוש פרמצבטיקה (ישראל) בע"מ</u>

מצהיר/ת בזאת כי תוכן העלון לצרכן במתכונת עלון לרופא המצ"ב תואם במלואו לעלון שהועבר בנוטיפיקציה למשה"ב בתאריך <u>מרץ 2021 (</u>Tecentriq PI version 8)

	Lily Adar	חתימה	15	-Mar-202	²¹ נאריך	n
		e: Lily Adar ason: I approve this docume e: 15-Mar-2021 4:50:03 PN				
(3 4982°00701 °2617	³ ถ้า ⁸ างoer <u>Tec</u>	entriq [®]	אם התכשיר:	IJ

אני הרוקח/ת האחראי/ת <u>מיכל קלייו</u> של בעל הרישום <u>רוש פרמצבטיקה (ישראל) בע"מ</u>

מתחייבת ליישם את העלון המעודכן באריזת התכשיר תוך 9 חודשים מיום אישורו בהתאם להוראות סעיף5.13 לנוהל "הנחיות להגשה ועדכון עלונים לרופא ולצרכן" או עפ"י הנחיות המחלקה לרישום תכשירים.

1	-DocuSign	ed by:		
	Michal	חתימה	15-Mar-2021	תאריך
	Signing R	me: Michal eason: I approve this document me: 15-Mar-2021 7:03:29 PM CET		
		8D4E54A92B87F5C39AA17F049		



Signatures: 2 Envelope Originator: Initials: 0 Bator Tsafari-Hagag Grenzachstrasse 124 Basel, Basel-Stadt 4070 Time Zone: (UTC+01:00) Amsterdam, Berlin, Bern, Rome, Stockholm, Vienna bator.tsafari-hagag@roche.com IP Address: 46.116.162.166 Status: Original Holder: Bator Tsafari-Hagag Location: DocuSign 3/15/2021 4:41:53 PM bator.tsafari-hagag@roche.com Signer Events Signature Timestamp Lily Adar Sent: 3/15/2021 4:43:31 PM Lily Adar lily.adar@roche.com Viewed: 3/15/2021 4:48:55 PM **Appointed Pharmacist** Signed: 3/15/2021 4:50:14 PM CFR Part 11 - Joint - Sub Account_310 Signature Adoption: Pre-selected Style Security Level: Email, Account Authentication Signature ID: (Required) 8822B57E-DB59-4743-8E3D-DA9D547F361B Using IP Address: 196.3.38.244 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document **Electronic Record and Signature Disclosure:** Accepted: 4/5/2020 9:03:11 AM ID: 626d9698-4caf-476c-b1c0-8f438320ac12 Company Name: F.Hoffmann-La Roche Ltd. - CFR Part 11 - Sub 3 Michal Sent: 3/15/2021 4:50:18 PM Michal michal.klein@roche.com Viewed: 3/15/2021 7:02:49 PM QP & Quality Unit Manager Signed: 3/15/2021 7:03:31 PM CFR Part 11 - Joint - Sub Account_310 Signature Adoption: Pre-selected Style Security Level: Email, Account Authentication Signature ID: (Required) 80770BC8-D4E5-4A92-B87F-5C39AA17F049 Using IP Address: 87.71.137.204 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document **Electronic Record and Signature Disclosure:** Accepted: 4/2/2020 2:52:58 PM ID: 8bdb284d-886a-4618-9902-2591f0e4d210 Company Name: F.Hoffmann-La Roche Ltd. - CFR Part 11 - Sub 3 In Person Signer Events Signature Timestamp **Editor Delivery Events** Status Timestamp

Status

Status

Certificate Of Completion

Envelope Id: 97E526D4E02547B8A5A24A1AAE08A281 Subject: Please DocuSign: Declaration for publication.pdf Source Envelope: Document Pages: 1 Certificate Pages: 4 AutoNav: Enabled EnvelopeId Stamping: Disabled

Record Tracking

Agent Delivery Events

Intermediary Delivery Events

Status: Completed

Timestamp

Timestamp

Certified Delivery Events	Status	Timestamp
Carbon Copy Events	Status	Timestamp
Witness Events	Signature	Timestamp
Notary Events	Signature	Timestamp
Envelope Summary Events	Status	Timestamps
Envelope Summary Events Envelope Sent	Status Hashed/Encrypted	Timestamps 3/15/2021 4:43:31 PM
		•
Envelope Sent	Hashed/Encrypted	3/15/2021 4:43:31 PM
Envelope Sent Certified Delivered	Hashed/Encrypted Security Checked	3/15/2021 4:43:31 PM 3/15/2021 7:02:49 PM
Envelope Sent Certified Delivered Signing Complete	Hashed/Encrypted Security Checked Security Checked	3/15/2021 4:43:31 PM 3/15/2021 7:02:49 PM 3/15/2021 7:03:31 PM

Guidelines for the use of the DocuSign electronic signing system within F. Hoffmann-La Roche and companies of the Roche Group

LEGAL DISCLOSURE

By placing my electronic signature on this document, I expressly consent to use and rely on Electronic and Digital Signatures and I understand my signature will have the same binding effect as if I was providing a handwritten signature.

I also confirm the email address that I am using as a valid one to be notified and identified electronically, for example through the DocuSign System, and/or to identify me as the signer of the document. I should inform Roche in the case that the email address changes.

CONSUMER DISCLOSURE

From time to time, F. Hoffmann-La Roche and companies of the Roche Group (hereinafter referred to as we, us or Company) may be required by law to provide to you certain written notices or disclosures. Described below are the terms and conditions for providing to you such notices and disclosures electronically through the DocuSign, Inc. (DocuSign) electronic signing system. Please read the information below carefully and thoroughly, and if you can access this information electronically to your satisfaction and agree to these terms and conditions, please confirm your consent by clicking the 'I agree' button at the bottom of this document.

Consequences of changing your mind

To indicate to us that you are changing your mind, you must withdraw your consent using the DocuSign 'Withdraw Consent' form on the signing page of a DocuSign envelope instead of signing it. This will indicate to us that you have withdrawn your consent to receive required notices and disclosures electronically from us and you will no longer be able to use the DocuSign system to receive required notices and consents electronically from us or to sign electronically documents from us.

All notices and disclosures will be sent to you electronically

Unless you tell us otherwise in accordance with the procedures described herein, we will provide electronically to you through the DocuSign system all required notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to you during the course of our relationship with you. To reduce the chance of you inadvertently not receiving any notice or disclosure, we prefer to provide all of the required notices and disclosures to you by the same method and to the same address that you have given us. If you do not agree with this process, please let us know as described below. Please also see the paragraph immediately above that describes the consequences of your electing not to receive delivery of the notices and disclosures electronically from us.

How to contact us

You may contact us to let us know of your changes as to how we may contact you electronically, to request certain information from us and to withdraw your prior consent to receive notices and disclosures electronically. To do so contact the sender of the envelope.

To advise us of your new email address

To let us know of a change in your email address where we should send notices and disclosures electronically to you, you must send an email message to the sender of the envelope and in the body of such request you must state: your previous email address, your new email address. We do not require any other information from you to change your email address. In addition, you must notify DocuSign, Inc. to arrange for your new email address to be reflected in your DocuSign account by following the process for changing email in the DocuSign system.

To withdraw your consent

To inform us that you no longer want to receive future notices and disclosures in electronic format you may decline to sign a document from within your DocuSign session, and on the subsequent page, select the check-box indicating you wish to withdraw your consent.

Acknowledging your access and consent to receive materials electronically

To confirm to us that you can access this information electronically, which will be similar to other electronic notices and disclosures that we will provide to you, please verify that you were able to read this electronic disclosure and that you also were able to print on paper or electronically save this page for your future reference and access or that you were able to email this disclosure and consent to an address where you will be able to print on paper or save it for your future reference and access. Further, if you consent to receiving notices and disclosures exclusively in electronic format on the terms and conditions described above, please let us know by clicking the 'I agree' button below.

By checking the 'I agree' box, I confirm that:

- I can access and read this Electronic CONSENT TO ELECTRONIC RECEIPT OF ELECTRONIC CONSUMER DISCLOSURES document; and
- I can print on paper the disclosure or save or send the disclosure to a place where I can print it, for future reference and access; and
- Until or unless I notify the account owner as described above, I consent to receive from exclusively through electronic means all notices, disclosures, authorizations, acknowledgements, and other documents that are required to be provided or made available to me by the account owner during the course of my relationship with you.
- I acknowledge the information included in the **DocuSign Privacy Policy**