Zeta **Corporation**

PO Box 282 **Tel: 626-355-2053** **Fax: 626-836-9149**
Sierra Madre, CA 91025-0282 www.zeta-corp.com

FSCA Reference: FSCA-1122024-001

Date: 1 February 2024

Urgent Field Safety Notice

For Attention of*:

Contact details of local representative (name, e-mail, telephone, address etc.)*
info@zeta-corp.com

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Urgent Field Safety Notice (FSN)

1. Information on Affected Devices
1. Device Type(s)*
Lab reagents
2. Commercial name(s)
Zeta Corp
3. Primary clinical purpose of device(s)*
IHC lab reagent
4. Device Model/Catalogue/part number(s)*
Please see attached
5. Affected serial or lot number range
Please see attached

2 Reason for Field Safety Corrective Action (FSCA)*
1. Description of the product problem*
The products do not have a valid notified body CE marking certificate to the IVDR to market these products that were launched after May 26, 2022. The products were mistakenly placed on the EU market with legacy product CE marking as changes to an existing device that were incorrectly deemed as non-significant.
2. Hazard giving rise to the FSCA*
Negligible; Missing or mis-labeling may provide wrong results.
3. Probability of problem arising
It most likely won't rising any problem
4. Predicted risk to patient/users
Products most likely won't risk patient/users due to the nature of the products.
5. Further information to help characterise the problem
Don't have approval to market the products in EU countries.

Commented [PE1]: This is a required field

Commented [PE2R1]: This does not actually answer what the hazard is.

Commented [EP3R1]: This is NOT a mislabeling. It is illegally marketing a device for which has no valid CE marking.

Commented [EP4R1]: Wrong results is not applicable

3. Type of Action to mitigate the risk*
1. Action To Be Taken by the User*
☐ Identify Device ☐ Quarantine Device Return Device ☒ Destroy Device
☐ On-site device modification/inspection
☐ Follow patient management recommendations

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☐ Take note of amendment/reinforcement of Instructions For Use (IFU) ☐ Other ☐ None Provide further details of the action(s) identified.	
2. By when should the action be completed?	ASAP: Feb 28, 2024
3. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes
4. Action Being Taken by the Manufacturer ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Provide further details of the action(s) identified.	
5. By when should the action be completed?	ASAP: Feb 28, 2024

Commented [EP5]: If you aren't collecting a response form, how will you reconcile? CAs will expect a response form.

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4. General Information*	
1. FSN Type*	New
2. Further advice or information already expected in follow-up FSN? *	No
3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN*)*	
a. Company Name	Zeta Corporation
b. Address	605 E Huntington Drive; #204; Monrovia, CA 91016
c. Website address	www.zeta-corp.com
4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * yes	
5. List of attachments/appendices:	www.zeta-corp.com
6. Name/Signature	Fanny Dang

Transmission of this Field Safety Notice
This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*