Ustar Biotechnologies (Hangzhou) Ltd.

Rev 2: February 2020

FSN Ref: CN-MF-000014615 / ANSM : R2602295 FSCA Ref: CN-MF-000014615

Date: 2026.02.09

Field Safety Notice
Device Commercial Name

For Attention of*:Distributors/Healthcare Facilities and End-Users (Laboratories/Clinicians)

Contact details of local representative (name, e-mail, telephone, address etc.)*
Nom : Lotus NL B.V. À l'attention de : Feifei Cao Adresse : Koningin Julianaplein 10, 1e Verd, 2595AA, La Haye, Pays-Bas. E-mail : info@lotusnl.com Téléphone : +31644168999

Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	DMDIV - Kit de détection du paludisme
1.	2. Commercial name(s)*
	EasyNAT Malaria Assay
1.	3. Unique Device Identifier(s) (UDI-DI)
	/
1.	4. Primary clinical purpose of device(s)*
	Le test est destiné à une détection qualitative rapide de l'acide désoxyribonucléique (ADN) du Plasmodium, y compris de Plasmodium vivax, Plasmodium malariae, Plasmodium falciparum, Plasmodium ovale et Plasmodium Knowlesi dans des échantillons de plasma humain, de sang total et de sang prélevé au bout du doigt.
1.	5. Device Model/Catalogue/part number(s)*
	U203010-20
1.	6. Software version
	/
1.	7. Affected serial or lot number range
	Lot : 20250225
1.	8. Associated devices
	/

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Ustar a confirmé qu'un dispositif programmé avec une version antérieure du code de l'algorithme de détection peut générer un résultat faux positif pour l'infection par le paludisme lors de l'utilisation du lot concerné (20250225).
2.	2. Hazard giving rise to the FSCA*
	Le risque majeur réside dans la génération d'un résultat faux positif, ce qui pourrait entraîner l'administration d'un traitement antipaludique inapproprié pour le patient.
2.	3. Probability of problem arising
	/
2.	4. Predicted risk to patient/users
	/
2.	5. Further information to help characterise the problem
	/
2.	6. Background on Issue
	/
2.	7. Other information relevant to FSCA
	/

3. Type of Action to mitigate the risk*		
3.	**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 ☒ Take note of amendment / reinforcement of Instructions For Use (IFU) ☒ Other ☐ None Veuillez suivre rigoureusement les instructions suivantes : Mettre immédiatement en quarantaine et cesser l'utilisation des lots de réactifs concernés (numéro de lot : 20250225). Vérifier que le dispositif utilise la dernière version du programme de détection avant de procéder à tout nouveau test. Scanner le code QR mis à jour fourni avec les kits de remplacement afin de synchroniser le logiciel. Signaler tout résultat suspecté d'être un faux positif ou un faux négatif au support technique d'Ustar.	
3.	2. By when should the action be completed?	/
3.	3. Particular considerations for: / Is follow-up of patients or review of patients' previous results recommended? / /	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Oui
3.	**5. Action Being Taken by the Manufacturer***	
	☐ Product Removal ☐ On-site device modification/inspection ☒ Software upgrade ☒ IFU or labelling change ☒ Other ☐ None Ustar remplacera les codes QR fournis avec le lot concerné (lot : 20250225) afin de garantir la compatibilité avec la version mise à jour du logiciel. De plus, Ustar mettra en œuvre des codes QR mis à jour pour tous les futurs lots de réactifs.	
3.	6. By when should the action be completed?	/
3.	7. Is the FSN required to be communicated to the patient /lay user?	/
3.	8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?	
	Choose an item. Choose an item.	

4. General Information*		
4.	1. FSN Type*	New
4.	2. For updated FSN, reference number and date of previous FSN	/
4.	3. For Updated FSN, key new information as follows:	
	/	
4.	4. Further advice or information already expected in follow-up FSN? *	No
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	/	
4.	6. Anticipated timescale for follow-up FSN	/
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	/
	b. Address	/
	c. Website address	/
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * Oui	
4.	9. List of attachments/appendices:	/
4.	10. Name/Signature	/

	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.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.