Rev 1: September 2018
FSN Ref: 2025-00001 FSCA Ref: 2025-00001

Date: 21/05/2025

Urgent Field Safety Notice
Device Commercial Name

For Attention of*:Responsible Body, Laboratory Manager, Users/operators.

Contact details of local representative (name, e-mail, telephone, address etc.)*
(1) Italia: Milestone s.r.l. – 24030 Valbrembo (BG), Via Italia, 3, 035.04010700 regulatory@milestonesrl.com; A. Menarini Diagnostics s.r.l. – 50012 Bagno a Ripoli (FI), Via Lungo L'Ema, 7, Telefono: 055.56081, inquiries@menarini.it;

Milestone s.r.l.

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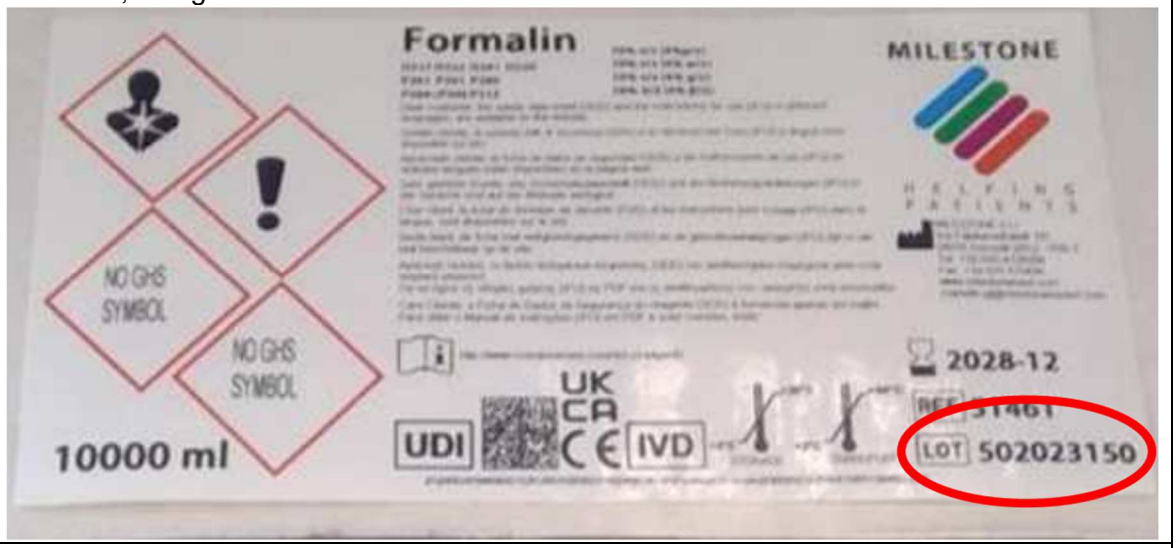
Urgent Field Safety Notice (FSN)
Device Commercial Name
Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Formalin, Reagente fissativo in tanica da 10 L. 
1.	2. Commercial name(s)
	Formalin
1.	3. Unique Device Identifier(s) (UDI-DI)
	8052478985084
1.	4. Primary clinical purpose of device(s)*
	Reagente fissativo.
1.	5. Device Model/Catalogue/part number(s)*
	51416
1.	6. Software version
	N.A.
1.	7. Affected serial or lot number range
	Lotti coinvolti: 202024170, 252024210, 312024020, 362024060 e 452024080.
1.	8. Associated devices
	FSCA: per dispositivi non ancora utilizzati.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Perdite di reagente dal contenitore.
2.	2. Hazard giving rise to the FSCA*
	Rischi legati ad utilizzatori professionali (nell'ambiente di utilizzo del dispositivo non vi sono presenti i pazienti), esposizione al reagente
2.	3. Probability of problem arising
	Provide an indication (from incident data or prospective modelling) of the likelihood the problem will arise.
2	4. Predicted risk to patient/users

.	From the output of the Health Hazard Evaluation indicate the anticipated risk (product of severity x probability) of patient/end user harm (direct or indirect).
2.	5. Further information to help characterise the problem
	Include any further relevant statistics to help convey the seriousness of the issue.
2.	6. Background on Issue
	Eg how the manufacturer became aware; brief details of relevant incidents; root cause if known; rationale for containment of problem to only affected devices; other risk mitigation or longer-term preventative action etc.
2.	7. Other information relevant to FSCA
	This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the 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

È richiesto l'isolamento e la distruzione delle taniche da 10 L dei lotti coinvolti.

3.	2. By when should the action be completed?	15 giorni lavorativi

3. 3. Particular considerations for: IVD

Is follow-up of patients or review of patients' previous results recommended?
No

Il reagente contenuto non crea nessun effetto negative ai pazienti ed alla preparazione del campione in sé. Aspetto legato alla perdita di reagente, legata alla esposizione del reagente stesso.

3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes

3. 5. Action Being Taken by the Manufacturer

☐ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☐ IFU or labelling change
☐ Other ☐ None

È richiesto riscontro dello smaltimento e per la sostituzione del dispositivo coinvolto.

3	6. By when should the action be completed?	Specify where critical to patient/end user safety
3.	7. Is the FSN required to be communicated to the patient /lay user?	N/A

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	Provide reference and date of previous FSN if relevant
4.	**3.** For Updated FSN, key new information as follows:	
	Stiamo effettuando verifiche interne sulle cause.	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Eg patient management, device modifications etc	
4	6. Anticipated timescale for follow-up FSN	For provision of updated advice.
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	**Milestone s.r.l.**
	b. Address	**Via Fatebenefratelli, 1/5 – 24010 Sorisole (BG)**
	c. Website address	**https://www.milestonemedsrl.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	If extensive consider providing web-link instead.
4.	10. Name/Signature	**PRESIDENTE, Visinoni Francesco** VSNFNC39H13Z315G/70280005034921 94.KzoFtufBHOvjCFqnrdIgAeRfVAU= Firmato digitalmente da VSNFNC39H13Z315G/7028000503492194.KzoFtufBHOvjCFqnrdIgAeRfVAU=; ND: C=IT, O=Non Dichiarato, OU=PROVINCIA DI PADOVA, CN=" VSNFNC39H13Z315G/7028000503492194.KzoFtufBHOvjCFqnrdIgAeRfVAU=", E=e.bramblla@milestonesrl.com, dnQualifier=20245063904A06, SERIALNUMBER=VSNFNC39H13Z315G, SN=VISINONI, G=FRANCESCO Motivo: Sto approvando il documento Posizione: Data: 2025.05.23 17:04:09+02'00' Foxit PDF Reader Versione: 2025.1.0

	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.