FSN Ref: **FSN_02-23** FSCA Ref: **FSCA_02-23**

Date: 05.12.2023.

Urgent Field Safety Notice (FSN)

Safety notice concerning possible contamination with Salmonella spp. within sheep blood, BIOSAP SO, LOT: 420269

For Attention of*: all users of BIOSAP SO, defibrinated sheep blood, reoxygenated, LOT: 420269.

Contact details of local representative (name, e-mail, telephone, address etc.)*
BIOGNOST Ltd., Medjugorska 59, 10040 Zagreb, biognost@biognost.hr

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Risk addressed by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Supplement for use in microbiology diagnostics.
1.	2. Commercial name(s)
	BIOSAP SO, Defibrinated sheep blood, re-oxygenated
1.	3. Unique Device Identifier(s) (UDI-DI)
	n/a
1.	4. Primary clinical purpose of device(s)*
	The product is used as a supplement to culture media for determining type of hemolytic reaction conducted by certain microorganisms and as culture media enhancer.
1.	5. Device Model/Catalogue/part number(s)*
	DOKO-050, DOKO-100, DOKO-250, DOKO-500
1.	6. Software version
	n/a
1.	7. Affected serial or lot number range
	LOT: 420269
1.	8. Associated devices
	n/a

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem*
	Manufactured batch 420269 of BIOSAP SO products was released in accordance with BioGnost's quality control criteria and a negative sterility test. After ten days on the market, we received a complaint from a customer about possible contamination with Salmonella spp.
2.	2. Hazard giving rise to the FSCA*
	False positive results on Salmonella spp. in patients during microbiological sample processing.
2.	3. Probability of problem arising
	Considering the partial contamination of batch 420269 at the end users, we believe that a small number of slow-growing bacteria was present in the raw sheep blood sample.
2.	4. Predicted risk to patient/users
	There is no risk for the patient, because there is no direct contact with the product, except for subsequent false positive results.
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 Provide further details of the action(s) identified.
3.	2. By when should the action be completed? — Fill out the attached confirmation and send it to BioGnost Ltd. by e-mail by 7 December 2023. Returning the confirmation is essential so we can confirm that you received the information.
3.	3. Particular considerations for: Choose an item. Is follow-up of patients or review of patients' previous results recommended? No Provide further details of patient-level follow-up if required or a justification why none is required
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return) — Yes (07.12.2023.)
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None 1. We inform our dear customers/distributors about a possible contamination with Salmonella spp. in sheep's blood, BIOSAP SO, LOT: 420269 and we instruct customers to stop using this product. 2. Send all customers a free replacement quantity of the product or a credit note. 3. We are actively investigating corrective measures to prevent future mistakes of this type.
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? — No
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:	
	Summarise any key difference in devices affected and/or action to be taken.	
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:	
	Eg patient management, device modifications etc	
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	**BioGnost Ltd.**
	b. Address	**Medjugorska 59, 100040 Zagreb, Croatia**
	c. Website address	**www.biognost.com**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * YES	
4.	9. List of attachments/appendices:	**1. FSN Distributor/Importer Reply Form**
4.	10. Name/Signature	**Ivana Šestak Panižić** **Quality Control and Security Manager** 

	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.