BioGnost Ltd.
Medjugorska 59, 10040 Zagreb, Croatia, EU
CRN 3595722 PIN 05273195306
VAT ID/EORI: HR05273195306
+385 1 2409 997
+385 1 2404 039
www.biognost.com
biognost@biognost.hr

Company certified to ISO 9001:2015 and ISO 13485:2016 quality management systems, and ISO 14001:2015 environmental management system

Date: 2023-04-17
Reference FSN number of the manufacturer: FSN_01/23
Reference FSCA number of the manufacturer FSCA_01/23

Field Safety Notice
Cresyl Violet, solution; Luxol Fast Blue kit

For Attention of: [redacted]

Contact details of local representative (name, e-mail, telephone, address etc.)
[redacted], Switzerland

Reference FSN number of the manufacturer: FSN-01/23
Reference FSCA number of the manufacturer FSCA-01/23

Field Safety Notice (FSN)
Cresyl Violet, solution; Luxol Fast Blue kit
Risk addressed by FSN

1. Information on Affected Devices	
1.	1. Device Type(s)
	Cresyl Violet, solution is a component of Luxol Fast Blue kit intended for staining of histological sections of brain tissue and spinal cord tissue. The kit is used for visualisation of myelin and Nissl bodies. Cresyl Violet, solution and Luxol Fast Blue kit are non-sterile products.
1.	2. Commercial name(s)
	Cresyl Violet, solution; Luxol Fast Blue kit
1.	3. Unique Device Identifier(s) (UDI-DI)
	385889212HPC30708STARVF
1.	4. Primary clinical purpose of device(s)
	Clinical purpose of devices Cresyl Violet, solution and Luxol Fast Blue kit (Cresyl Violet solution being one of the components of Luxol Fast Blue staining kit which cannot be used separately) is to visualize structures and components of nerve tissue – brain and spinal cord. Formalin-fixed histological samples of brain and spinal cord are being processed and then cut to a very thin sections on a microtome. The next step is staining sections with Luxol Fast Blue staining kit. Stained slides are then being examined under the light microscope.
1.	5. Device Model/Catalogue/part number(s)
	Catalogue numbers are: for Cresyl Violet, solution CV-OT-100 and for the Luxol Fast Blue kit LFB-100T.
1.	6. Software version
	/
1.	7. Affected serial or lot number range
	For Cresyl Violet, solution: CV-10/21 and CV-12/22. For Luxol Fast Blue kit: LFB-14/21, LFB-16/22 and LFB-17/22.
1.	8. Associated devices
	Cresyl Violet, solution is only associated to Luxol Fast Blue kit.

2. Reason for Field Safety Corrective Action (FSCA)	
2.	1. Description of the product problem
	Cresyl Violet, solution has lost its staining capacity (quality deterioration of the reagent) and the staining of the slides could not be accomplished.
2.	2. Hazard giving rise to the FSCA
	Greatest hazard to the patient is that the diagnosis could not be made when using Luxol Fast Blue kit with non-compliant Cresyl Violet, solution. Sample slide would remain unstained, making it impossible to visualise cell structures on the slide.

Reference FSN number of the manufacturer: FSN-01/23
Reference FSCA number of the manufacturer FSCA-01/23

2.	3. Probability of problem arising
	Probability is low because there are other special staining methods including IHC staining for nerve tissue.
2.	4. Predicted risk to patient/users
	/
2.	5. Further information to help characterise the problem
	/
2.	6. Background on Issue
	After we received the complaint from a customer that Cresyl Violet solution does not stain the slide, we conducted investigation internally in Quality Control department. Complaint was received from a customer who used it differently from the intended usage defined by the manufacturer. Nevertheless, stored controlled samples of the Cresyl Violet solution, batches number CV-10/21 and CV-12/22 showed deterioration in staining intensity. Root cause was identified as a problem with system for water demineralization – system was afterwards serviced and is being regularly maintained. As a preventive action, Cresyl Violet solution will be buffered at a certain point optimal to Cresyl Violet dye to omit the varying of the pH value and consequently the instability Cresyl Violet dye. Another preventive action will include more chemically resistant packaging – depending on the volume, Cresyl Violet solution will be packed in amber glass bottles, HDPE bottles or fluorinated LDPE dropper bottles. Final decision will be made after the initial results of the stability studies.
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 If the device is in stock at the distributors' warehouse or the end user has it, device can be destroyed or disposed accordingly. The user can dispose it by itself or it can be handled to the distributor for a disposal.

Reference FSN number of the manufacturer: FSN-01/23
Reference FSCA number of the manufacturer FSCA-01/23

3.	2. By when should the action be completed?	Specify where critical to patient/end user safety. By 20 April, 2023.
3.	3. Particular considerations for: IVD Is follow-up of patients or review of patients' previous results recommended? No /	
3.	4. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes, by the April 20, 2023.
3.	**5. Action Being Taken by the Manufacturer** ☒ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☐ Other ☐ None Distributors and buyers are being notified and the products are being withdrawn from the market.	
3.	6. By when should the action be completed?	July 1, 2023
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.	

Reference FSN number of the manufacturer: FSN-01/23
Reference FSCA number of the manufacturer FSCA-01/23

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?	Yes
4.	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Device modifications – buffer addition to the composition of the Cresyl Violet solution and change of the packaging	
4.	6. Anticipated timescale for follow-up FSN	Beginning of the July 2023
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, 10040 Zagreb, Croatia
	c. Website address	www.biognost.hr
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. YES	
4.	9. List of attachments/appendices:	/
4.	10. Name/Signature	Ivana Sestak Panizic, Head of Quality Assurance
		BIOGNOST BIOGNOST d.o.o., www.biognost.hr Medjugorska 59, 10040 Zagreb, Croatia

	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.