GELITA MEDICAL GmbH • Uferstraße 7 • 69412 Eberbach

To Whom It May Concern

GELITA MEDICAL GmbH
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Date July 16, 2021

FSN reference: CR-21-014

Urgent Field Safety Notice
GELITA-SPON® RAPID³ (R00107/4)

For Attention of*:

BfArM - Bundesinstitut für Arzneimittel und Medizinprodukte
Kurt-Georg-Kiesinger-Allee 3
53175 Bonn, Germany

No immediate risk is expected as the endotoxin limits of product were not exceeded, but to minimize the risk the product still left in warehouse must be quarantined and destroyed.

Contact details of local representative (name, e-mail, telephone, address etc.)*
Dr. Sheetal Gangula, Uferstarsse 7, 69412 Eberbach **Sheetal.Gangula@gelitamedical.com**

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

	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Absorbable Gelatin Sponge Hemostat, USP
1.	2. Commercial name(s)
	GELITA-SPON® RAPID^3
1.	3. Unique Device Identifier(s) (UDI-DI)
	4260293130020
1.	4. Primary clinical purpose of device(s)*
	Topical hemostat for use as an adjunct to hemostasis by tamponade effect, in particular where control of capillary, venous, and arteriolar bleeding, by pressure, ligature, and other conventional procedures, is either ineffective or impractical.
1.	5. Device Model/Catalogue/part number(s)*
	GR-310
1.	6. Software version
	N/A
1.	7. Affected serial or lot number range
	R00107/4
1.	8. Associated devices
	N/A

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	In a suspected OOS with other batch the Endotoxin level in this batch (R00107/4) was also tested and product showed Endotoxin result as 18.7 USP-EU/Sample (10 small sponges-blister), that means 1.87 USP-EU/cube, it is still in way below allowed limit (20 USP-EU/Sample (cube) for blood, tissue and bone contact). Moreover, it is highly possible that the values are higher due to laboratory error, investigation is on-going.
2.	2. Hazard giving rise to the FSCA*
	Given the tested amount within the limit, no hazard is identified for this batch. But to be on a safe side the complete batch is re-called. For an operation an average of 5 small gelatin cubed are used in one particular surgical location. Taking this into consideration, together with the generally tolerable endotoxin level of ≤5 EU/kg, patients > 1.87 kg are within the tolerance of the maximum amount of endotoxins and no fever reaction is expected. For a worst case scenario of 15 gelatin sponges used for a patient patients > 5.61 kg are within the tolerance of the maximum amount of endotoxins and no fever reaction is expected. 5 gelatin sponges used:

	1.87 USP-EU/ sample * 5 sponges = 9.35 USP-EU level in the human body / 5 EU/kg = 1.87 kg 15 gelatin sponges used: 1.87 USP-EU/ sample * 15 sponges = 28.05 USP-EU level in the human body / 5 EU/kg = 5.61 kg In a normal scenario and worst case scenario risk to the general population is negligible and moreover in a normal scenario the endotoxins are within tolerable limits. Due to the on-going investigation we are doing the re-call to be on the safe side.
2.	3. Probability of problem arising
	Only 12 boxes from this batch are shipped to 2 distributors (each 12 boxes). Both the distributors are supplying to different hospitals, from this 9 boxes received by first distributor were sent to 5 different hospitals and the second distributor sent out 10 boxes to customers. It can be concluded that the probability of fever occurrence is improbable as the use of these sponges is in general population and over use of sponges from all blister is one patient in a single hospital is a unforeseen situation, Therefore, the hazard occurrence probability is "P ≤ 10−6 (P ≤ 1/1.000.000)"
2.	4. Predicted risk to patient/users
	Given the above explanation in 2.2 (Hazard) and 2.3 (probability of occurrence), the severity can be down classified to negligible and probability of the immediate hazard arising can be rated as improbable.
2.	5. Further information to help characterize the problem
	N/A
2.	6. Background on Issue
	During a routine analysis one of the batch not yet released to the customers was found with higher endotoxin values, as part of the investigation also this batch (R00107/4) was analyzed and was found with Endotoxin limit near to the allowed limit, when one blister with10 cubes was tested. Therefore, to be on the safe side the complete batch is re-called.
2.	7. Other information relevant to FSCA
	N/A

	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?	Immediately upon receipt of this notice
3.	3. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? YES	
3.	4. Is customer Reply Required? * (If yes, form attached specifying deadline for return)	Yes, form attached to this FSN
3.	**5. Action Being Taken by the Manufacturer** To destroy or quarantine the unused devices.	
3	6. By when should the action be completed?	As soon as possible in the next working days upon receipt of this notice
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	N/A
4.	**3.** For Updated FSN, key new information as follows:	
	N/A	
4.	4. Further advice or information already expected in follow-up FSN? *	Not planned yet
	5. If follow-up FSN expected, what is the further advice expected to relate to:	

4	No follow up FSN is expected	
4	6. Anticipated timescale for follow-up FSN	N/A
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Only necessary if not evident on letter-head.
	b. Address	Only necessary if not evident on letter-head.
	c. Website address	**https://www.gelitamedical.com/**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * These devices were sold to customers in Germany, both the competent authority and notified body will be informed.	
4.	9. List of attachments/appendices:	**N/A**
4.	10. Name/Signature	Dr. Sheetal Gangula, RA/QM Director. 

	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..*