



FSN Ref: CR-22-006

FSCA Ref: CR-22-006

Date: 2022-07-21

Field Safety Notice

GELITA-SPON® STANDARD
GELITA-SPON® RAPID3
GELITA® ENT X-BLOD
GELITA® ENT X-DENSE
GELITA® ENT X-PAND
GELITA® ENT X-PASTE
GELITA-SPON® POWDER

For Attention of*:MEDIVAR OÜ, Ehitajate tee 114, 13517 Tallinn, Estonia

- **A risk to patients has been unidentified, as the endotoxin limit/specification for GELITA-SPON products has in a few cases been exceeded.**
- **Not all product has been found to be out of specification for endotoxins.**
- **Nevertheless, as the contamination is not homogenous, and outliers have been detected for some lots, GELITA MEDICAL has decided to issue this FSN and preventively recall all GELITA SPON product.**
- **If the product has already been used in patients and there was no acute inflammatory/pyrogenic response, it is unlikely that you received the contaminated product.**

Contact details of local representative (name, e-mail, telephone, address etc.)*

GELITA MEDICAL GmbH
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Field Safety Notice (FSN)
GELITA-SPON[®] STANDARD
GELITA-SPON[®] RAPID3
GELITA[®] ENT X-BLOD
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GELITA-SPON[®] POWDER
Risk of endotoxin poisoning

1. Information on Affected Devices*	
1.	<p style="text-align: center;">1. Device Type(s)*</p> <p>The following devices are the subject of this FSN:</p> <ul style="list-style-type: none"> • GELITA-SPON[®] STANDARD • GELITA-SPON[®] RAPID3 • GELITA[®] ENT X-BLOD • GELITA[®] ENT X-DENSE • GELITA[®] ENT X-PAND • GELITA[®] ENT X-PASTE • GELITA-SPON[®] POWDER <p>All products are absorbable gelatine-based hemostats and are supplied sterile.</p>
1.	<p style="text-align: center;">2. Commercial name(s)*</p> <p>As given above</p>
1.	<p style="text-align: center;">3. Unique Device Identifier(s) (UDI-DI)</p> <p>Appended in Annex I</p>
1.	<p style="text-align: center;">4. Primary clinical purpose of device(s)*</p> <p>Topical absorbable 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.</p>
1.	<p style="text-align: center;">5. Device Model/Catalogue/part number(s)*</p> <p>Appended in Annex I</p>
1.	<p style="text-align: center;">6. Software version</p> <p>No software is included with this device</p>
1.	<p style="text-align: center;">7. Affected serial or lot number range</p> <p>This recall is not limited to a particular batch number for the reasons described below. All products described above, still within shelf-life are being recalled. The shelf-life of these products is 5 years.</p>
1.	<p style="text-align: center;">8. Associated devices</p> <p>There are no associated devices.</p>



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2. Reason for Field Safety Corrective Action (FSCA)*	
2.	<p>1. Description of the product problem*</p> <p>In re-testing ordered by the manufacturer, the endotoxin concentration of the product in some samples has been measured above the limit. Since these “outliers” in testing cannot be reconciled at this time, GELITA MEDICAL GmbH, has decided to take a very conservative approach and recall all product, even that found to be within specification.</p>
2.	<p>2. Hazard giving rise to the FSCA*</p> <p>Bacterial endotoxins, found in the outer membrane of gram-negative bacteria are members of a class of phospholipids called lipopolysaccharides (LPS). LPS are not exogenous products of gram negative bacteria. Endotoxin is commonly found everywhere in the environment and it is the most significant pyrogen in parenteral drugs and medical devices. The release of LPS from bacteria takes place after death and lysis of the cell. Endotoxins can elicit a pyrogenic/inflammatory response from the human body. In rare cases, septic or anaphylactic shock might occur.</p>
2.	<p>3. Probability of problem arising</p> <p>The probability of the problem arising is considered to be “improbable” (1 in 1,000,000 patients) given the number of units sold (10,337,598 pieces since 2011) and that to date, no events have been reported to GELITA MEDICAL GmbH, possibly related to Endotoxin poisoning.</p>
2.	<p>4. Predicted risk to patient/users</p> <p>If the hospital received a contaminated product, an acute pyrogenic reaction might be expected within 2-5 days after use.</p>
2.	<p>5. Further information to help characterize the problem</p> <p>Statistics quantifying or qualifying the problem are not available to date. As discussed, there are “outliers” in the Endotoxin levels which cannot be explained or related to production, process, dates, raw materials, etc..</p>
2.	<p>6. Background on Issue</p> <p>In routine bioburden testing, higher than acceptable levels of Endotoxins were observed. This product was immediately recalled. Other batches, within specification, were put on hold until a proper root cause analysis (RCA) had been conducted. This RCA is still in progress and is examining end-to-end the production process for all possible sources of this contamination. Meanwhile, a viable process for eliminating Endotoxins is thought to have been identified. Product produced using a thermal hardening or cross-linking process, namely GELITA TUFT-IT gelatine hemostat has never exceeded the requisite Endotoxin levels, consequently, this process step is now being evaluated for the GELITA SPON products itemized above.</p>
2.	<p>7. Other information relevant to FSCA</p> <p>No other information is required</p>



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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?	
	Not Applicable	



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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:	
	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? *	Choose an item.
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	Only necessary if not evident on letter-head.
	b. Address	Only necessary if not evident on letter-head.
	c. Website address	Only necessary if not evident on letter-head.
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Annex 1 to GMED_FSN_July2022
4.	10. Name/Signature	<p style="text-align: center;">DocuSigned by: <i>Susan Klymowsky</i> 48EB16FFB062417...</p> <p style="text-align: center;">Susan Klymowsky PRRC</p> <p style="text-align: center;">DocuSigned by: <i>Stefanie Dettlinger</i> 3617388726E341A...</p> <p style="text-align: center;">Stefanie Dettlinger Regulatory & Quality Affairs Manager</p>



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Transmission of this Field Safety Notice	
	<p>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)</p> <p>Please transfer this notice to other organisations on which this action has an impact. (As appropriate)</p> <p>Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>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.*</p>

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