

Date: 11/06/2021

Urgent Field Safety Notice
NEX D1 DRY surgical brush/sponge

For Attention of the Distributor*

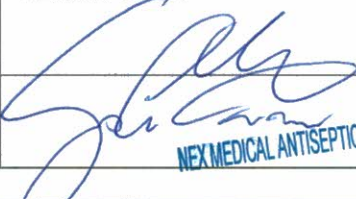
*Please refers to the recipient of the Recall Letter in attachment

Urgent Field Safety Notice (FSN)
NEX D1 DRY surgical brush/sponge
Risk addressed by FSN

1. Information on Affected Devices*	
1	1. Device Type(s)*
.	GMDN 39400 - brush, scrub, operating room
1	2. Commercial name(s)
.	NEX D1 DRY - surgical brush/sponge
1	3. Unique Device Identifier(s) (UDI-DI)
.	/
1	4. Primary clinical purpose of device(s)*
.	Sterile surgical brush-sponges, for antiseptic solutions dispensing and wound cleansing procedures
1	5. Device Model/Catalogue/part number(s)*
.	REF 0001
1	6. Software version
.	/
1	7. Affected serial or lot number range
.	Refer to the letter already provided
1	8. Associated devices
.	/

2 Reason for Field Safety Corrective Action (FSCA)*	
2	1. Description of the product problem*
.	The listed batch numbers are signaled by the sterilization plant SterilMilano srl to had been affected by deviations in ethylene oxide cycle. The cycles reports were falsified in order to show the full conformity of such cycles to the validation. Therefore the SAL 10 ⁻⁶ sterility is not ensured.
2	2. Hazard giving rise to the FSCA*
.	the sterility SAL 10 ⁻⁶ sterility is not ensured.
2	3. Probability of problem arising
.	/
2	4. Predicted risk to patient/users
.	No incidents on patients have been reported due to the risk of non-sterility of the device. The risk assessment for the infection risk is 10 ⁻⁴ (based on sterility tests and biological indicator tests independently performed on all batches), the risk is updated 10 ⁻⁶ after the recall and MIR action.
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* <input type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input type="checkbox"/> Return Device <input checked="" type="checkbox"/> Destroy Device <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Follow patient management recommendations <input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU) <input type="checkbox"/> Other <input type="checkbox"/> None Provide further details of the action(s) identified.	
3.	2. By when should the action be completed?	/ Specify where critical to patient/end user safety
3.	3. Particular considerations for: / Is follow-up of patients or review of patients' previous results recommended? /	
3.	4. Is customer Reply Required? *	Yes
3.	5. Action Being Taken by the Manufacturer <input checked="" type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection <input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change <input type="checkbox"/> Other <input type="checkbox"/> None	
3	6. By when should the action be completed?	10th July 2021
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	NA
4.	3. For Updated FSN, key new information as follows:	
	NA	
4.	4. Further advice or information already expected in follow-up FSN? *	
4	5. If follow-up FSN expected, what is the further advice expected to relate to:	
	Is expected to receive the quantities in stock at end-users and their confirmation of destruction.	
4	6. Anticipated timescale for follow-up FSN	10th July 2020
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Nex Medical Antiseptics s.r.l.
	b. Address	via per Arluno 37/39, 20010 Casorezzo (MI) - Italy
	c. Website address	www.nexmedical.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	Recall letter (including the list of recalled batches)
4.	10. Name/Signature	Tiziano Golzi
		 NEXMEDICAL ANTISEPTICS S.R.L.

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.