Rev 1: September 2018
FSN Ref: 01/2021 FSCA Ref: 01/2021

Date: 27.10.2021

Urgent Field Safety Notice
HYAMIRA FORTE
Batch N. 0306621

For Attention of*: Economic operators of medical devices and health products, physicians, patients and all interested parties

Contact details of local representative (name, e-mail, telephone, address etc.)*
Dott. Paolo Pizzoni, email: info@nyumapharma.it, telefono: +39 (0) 322 600623, address Nyuma Pharma S.r.l., via San Carlo 56, Arona (NO) - 28041 – Italy

Company Name/Logo

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

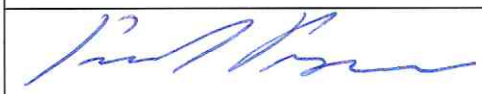
	1. Information on Affected Devices*
1.	1. Device Type(s)*
	Hyamira Forte is a sterile, injectable, non-pyrogenic, reabsorbable medical device made of reticulated hyaluronic acid of non-animal origin, produced via bacterial fermentation. Hyamira is colourless gel contained in a pre-filled, graduated, disposable and sterile syringe with Luer adapter
1.	2. Commercial name(s)
	Hyamira Forte
1.	3. Unique Device Identifier(s) (UDI-DI)
	N.A.
1.	4. Primary clinical purpose of device(s)*
	Hyamira Forte is intented to be used as a temporary filler to correct small skin defects, such as wrinkles or scars. It is also indicated for conditions such as HIV-associated lipodystrophy. In particular it is recommended for the treatment of deep facial wrinkles.
1.	5. Device Model/Catalogue/part number(s)*
	40223
1.	6. Software version
	N.A.
1.	7. Affected serial or lot number range
	Batch: 0306621 Production date: 29.09.2021 – Expiry date 28.09.2024
1.	8. Associated devices
	Needle manufactured by TSK Laboratory, Japan (2-1-5 Hirayanagi-Cho Tochigi-Shi, Tochigi-Ken 328-0012 Japan) EC-REP: Emergo Europe BV Prinsessegracht 20, 2514 AP The Hague, Netherlands.

	2 Reason for Field Safety Corrective Action (FSCA)*
2.	1. Description of the product problem*
	On October 20th, 2021 Nyuma Pharma s.r.l. has been informed about the theft of a batch of medical device Hyamira Forte that happened at the warehouse of the company specialized in cellophane wrapping. The theft has been immediately reported to police. As the above mentioned batch is now out of the approved supply and distribution chain, the Manufacturer cannot guarantee the maintenance of the safety and efficacy characteristics of the batch N. 0306621
2.	2. Hazard giving rise to the FSCA*
	Possible use of medical devices that might have been stored or handled in wrong conditions and placed on the market through unauthorized sales channels.
2.	3. Probability of problem arising
	Potentially 100% of the batch could be resold through unauthorized channels. Total pieces stolen: 2.516
2.	4. Predicted risk to patient/users
	Clinical adverse events due to the change of product's features
2.	5. Further information to help characterise the problem
	N.A.

2.	6. Background on Issue
	On October 20th, 2021 Nyuma Pharma s.r.l. has been informed about the theft of the batch N.0306621 (total units 2.516) of the medical device Hyamira Forte that happened at the warehouse of the company specialized in cellophane wrapping. The theft has been immediately reported to the police. The recurrence of the risk can not be mitigated by the Manufacturer as the root cause is of an exogenous nature independent from its control
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 Share information with all interested parties. In case a medical device batch n. 0306621 is retrieved contact the Manufacturer to the email address info@nyumapharma.it or by phone +39 0322 600623	
3.	2. By when should the action be completed?	As soon as the batch is identified
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)	No
3.	**5. Action Being Taken by the Manufacturer** ☐ Product Removal ☐ On-site device modification/inspection ☐ Software upgrade ☐ IFU or labelling change ☒ Other ☐ None FSN sent to Italian Ministry of Health. Notice to be sent to the supply chain.	
3	6. By when should the action be completed?	From the date 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?
	No Not appended to this FSN

	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:	
	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:	
	N.A.	
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	**Nyuma Pharma s.r.l.**
	b. Address	**Via San Carlo 56 – 28041 Arona**
	c. Website address	**www.nyumapharma.it**
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. *	
4.	9. List of attachments/appendices:	**N.A.**
4.	10. Name/Signature	**Paolo Pizzoni**
		

	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.