Urgent Field Safety Notice (FSN)
Device Names as provided in Appendix 1
Risk addressed by FSN

1. **Information on Affected Devices***	
1.	1. Device Type(s)*
	See Appendix 01
1.	2. Commercial name(s)
	See Appendix 01
1.	3. Unique Device Identifier(s) (UDI-DI)
	Not available
1.	4. Primary clinical purpose of device(s)*
	See Appendix 01
1.	5. Device Model/Catalogue/part number(s)*
	See Appendix 01
1.	6. Software version
	Not relevant
1.	7. Affected serial or lot number range
	See Appendix 01
1.	8. Associated devices
	Unknown.

2 Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the product problem
	Sidam has become aware of sterilization issues notified by the contract sterilizer Steril Milano, with potential impact on efficacy of the Ethylene Oxide (EtO) sterilization processes at Steril Milano (Monza site) and sterile status of the devices placed on the market. The quality issues detected by SterilMilano, during an internal audit, is due to their falsification of the cycle graphs and the manual editing of the EtO treatment certificates, in order to make them match with the new graphs associated to the cycles. Based on the controls of the tracking records of the falsified graphs, the frequency of tampering appears to be high (several times per week) and that this procedure has been in place since 2018. The last communication received on 31 March 2021 from the contract sterilizer SterilMilano highlighted also that the EO process validations were also impacted by falsifications in the related treatment cycle parameters and sensor results, which jeopardise the results of overall sterilization activities. As of today the raw data review performed by SterilMilano is related to the years 2019, 2020 and 2021. The falsification is related to different parameters of the following process phases: ▪ Preconditioning cycle ▪ Sterilization cycle ▪ Degassing cycle

2.	2. Hazard giving rise to the FSCA
	The falsification of relevant data especially linked to the preconditioning cycle and the sterilization cycle could play a crucial role respectively in the functionality and in the effectiveness of the sterilization processes of the devices. The ineffective sterilization of the devices used for infusion of drugs or devices with direct contact with tissues could have consequences for patient's health with potential side effects linked to unsterile products, patient infection and worsening of their health conditions. The falsification of the degassing cycle may have consequences in the Ethylene Oxyde residues and thus a potential risk for operators, users and patient's health, even if it has to be highlighted that the gas residues disappear after few days from sterilization phase. Being the devices placed on the market since years, this risk is considered negligible.
2.	3. Probability of problem arising
	As results of the Health Hazard Evaluation, approximately 16 % of the devices could arise the issues.
2.	4. Predicted risk to patient/users
	From the Health Hazard Evaluation, exposure to the microbiological contamination could lead to systemic infection and worsening of the patient health conditions. The Ethylene Oxyde residues could lead to exposure to cancerogenic chemical elements and related risks. The estimated likelihood to cause harm will be determined based on the number use remaining devices in the field, still not used for their clinical applications. In the worst-case conditions, assuming all devices not used yet, the probability to have injury which require medical intervention is frequent (P-harm > 1/1.000).
2.	5. Further information to help characterise the problem
	See Appendix 03_Interim Investigation report Steril Milano fraud
2.	6. Background on Issue
	See Appendix 03_Interim Investigation report Steril Milano fraud
2.	7. Other information relevant to FSCA
	See Appendix 03_Interim Investigation report Steril Milano fraud

	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 Once received this official notification, in order to prevent potential impact of the medical therapy, each user shall: 1) Identify and segregate all items listed in Appendix 01, still available at their premises,

2) Fill the acknowledgment letter provided in the Appendix 02, including the number of segregate devices and returned devices,

3) Within 5 working days from receiving the official notification, return all the segregated devices to Mr. Marco Tognolo, at Sidam premises, Strada Statale Sud, 171, 41037 Mirandola MO, Italy

As required, we have provided this notification to the relevant Regulatory Agencies of the countries where the devices have been distributed.

Please refer to your local sales agent for any further information you may need or, in alternative, contact directly Sidam customer service at telephone number 0535 25523 or mail FSCA@sidamit.it

3. **2. By when should the action be completed?**

Within 5 (five) calendar days from the issue date

ID#	Actions description	By when
1	Identify and segregate all items listed in Appendix 01, still available at users premises	Immediately or within 1 calendar day
2	Fill the Acknowledgment Letter provided in the Appendix 02, including the number of received devices, used devices, remaining and segregated devices.	Within 2 calendar days from the receipt of the present communication
3	Return all the segregated devices to Mr. Marco Tognolo, at Sidam premises, Strada Statale Sud, 171, 41037 Mirandola MO, Italy	Within 5 calendar days from receiving the official notification

3. **3. Particular considerations for:**

N/A

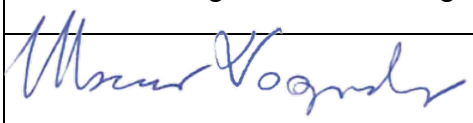
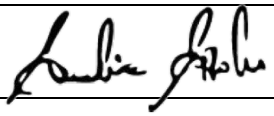
3. **4. Is customer Reply Required?**
See Acknowledgment Letter in Appendix02, to be returned within 2 calendar days from the issue date.

3. **5. Action Being Taken by the Manufacturer**

☒ Product Removal ☐ On-site device modification/inspection
☐ Software upgrade ☐ IFU or labelling change
☒ Other Device re-working ☐ None

	Based on the evaluation and sterility test performed, as conservative approach and a protective measure to maintain patient health, we decided to recall the devices listed in Appendix 01. Sidam has sent a Field Safety Notice to all affected customers. The Field Safety Notice identifies the problem, the affected products, the risk factors and the actions that must be taken by the users and distributors.	
3	**6. By when should the action be completed?**	Before 5 calendar days from the issue date
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?**	
	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	NA
4.	**3.** For Updated FSN, key new information as follows:	
	NA	
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:	
	NA	
4	6. Anticipated timescale for follow-up FSN	NA
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	Sidam srl a Socio Unico
	b. Address	Strada Statale Sud, 169, 41037 Mirandola MO - Italy
	c. Website address	http:// www.sidamgroup.com
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. Yes	
4.	9. List of attachments/appendices:	**1. Appendix 01: List of affected devices Ver1.0** **2. Appendix 02: Acknowledgment letter Ver1.0** **3. Appendix 03: Interim Investigation report Steril Milano fraud_v5**

4.	4. Name/Signature	Insert Name and Title here and signature below Marco Tognolo, QA Manager  08 Apr 2021
		Insert Name and Title here and signature below Annalisa Azzolini, CEO
		 08 Apr 2021

	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 and to all users 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.