Urgent Field Safety Notice
Device Commercial Names as provided in Appendix 1

To the kind attention of:

List of will be part of the FSN in the different destination countries

- Customer Name,
- Address
- Postal code, City name
- e-mail
- Telephone

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

This letter contains important information which require your **immediate attention**.

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
	C.G.M. Divisione Medicale Meta is the legal manufacturer of the following devices: 1. sterile scraper for use as a collecting bone flakes in oral surgical operations. 2. Set for Uterine Suction with tube and canula 3. membrane fixation tacks for oral surgical operations 4. Umbilical Cord Clamp 5. Closed Circuit Urine Bag 6. Amniotic Membrane Perforator 7. Magnetic Mat for Surgical Instrument Those products are supplied to the market in sterile status, following the Etylene Oxide sterilization process performed overtime by Steril Milano Srl, one of the largest EO sterilization service providers in Italy. C.G.M. Divisione Medicale Meta 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 the contract sterilizer Steril Milano and sterile status of the devices placed on the market. According to our investigation, we have identified certain batches for which we are unable to guarantee the primary sterility, even though, for the time being, based on our

	test results, we have no evidence of non-sterile status of the goods. Those batches are listed in the attached **Appendix 1 "List of Impacted Batches"**.
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 in the functionality and effectiveness of the devices' sterilisation processes. As specified in the risk analysis of the technical files, the ineffective sterilization of the devices listed above, could have consequences for patient's health with potential side effects linked to unsterile products, patient infection and worsening of their health conditions. C.G.M. Medical Division META didn't receive any notification of adverse events or serious patient harm associated with this safety corrective action. Even in the past years, our company didn't receive claims for adverse events referred to the millions of devices sold. Based on the following reasons, no specific patient follow-up activities are required for the product used:1) a preventive antibiotic therapy is prescribed before surgery procedures, 2) low level of microbial contamination of the products - detected by periodic Bioburden Tests - guarantee good disinfection of devices,3) no adverse events occurred for over 2 Million products sold in over 20 years, 4) Several Sterility Tests performed on devices sterilised with batches affected by this FSN resulted "sterile". 5) The sterilization colour change indicators are always checked during incoming controls and no deviation was never detected.All the products identified as potentially not sterile delivered to your Company are listed in Appendix 1 "List of Impacted Batches of the present FSN".
2.	3. Probability of problem arising
	All analysis performed in the past shown that the products were correctly sterile. Right now, further analysis is ongoing. Therefore we can't define a percentage, yet.
2.	4. Predicted risk to patient/users
	From the Health Hazard Evaluation of our devices, exposure to microbiological contamination could lead to bacterial infection and worsening of the patient health conditions.
2.	5. Further information to help characterise the problem
	NA
2.	6. Background on Issue
	NA
2.	7. Other information relevant to FSCA
	NA

	3. Type of Action to mitigate the risk
3.	**1. Action To Be Taken by the User** ☒ Identify Device ☒ Quarantine Device ☒ Return Device, when requested by C.G.M. Divisione Medicale Meta ☒ Destroy Device, when requested by C.G.M. Divisione Medicale Meta ☐ 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 procedure, each user shall: 1) Identify and segregate all items listed in Appendix 01, still available at their premises, 2) Translate FSCA and Acknowledgment letter for Healthcare Facilities, provided in Annex 03, in your national languages, 3) Fill in the acknowledgment letter provided in the Appendix 02, including the number of segregate devices and returned devices, 4) Within 5 working days from receiving the official notification, return to C.G.M. Divisione Medicale Meta premises, E.Villa n.7, I-42124 Reggio Emilia (RE) – Italy, or destroy all the segregated devices, according to instruction provided by META, 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 C.G.M. Divisione Medicale Meta customer service at telephone number +39 0522 502311 or mail helpdesk@metahosp.com
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 your premises	Immediately or within 1 calendar day
2	Translate FSCA and Acknowledgment letter for Healthcare Facilities, provided in Annex 03, in your national languages	Immediately or within 3 calendar day

	3	Fill the Acknowledgment Letter provided in the Appendix 02, including the number of received devices, used or sold devices, remaining and segregated devices.	Within 7 calendar days from the receipt of the present communication
	4	Return to C.G.M. Divisione Medicale Meta premises, Via E.Villa n.7, I-42124 Reggio Emilia (RE) – Italy, or destroy all the segregated devices, according to instruction provided by META	Within 15 calendar days from receiving the official notification

3.	**3. Particular considerations for:** N/A	
3.	**4. Is customer Reply Required?** See Acknowledgment Letter in Appendix 02, to be returned within 7 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 replace the devices listed in Appendix 01. C.G.M. Divisione Medicale Meta 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 30 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	C.G.M. Divisione Medicale Meta S.p.A.
	b. Address	Via E.Villa n.7, I-42124 Reggio Emilia (RE) – Italy
	c. Website address	http://www.metahosp.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. <u>Appendix 01: List of affected devices</u>** **2. <u>Appendix 02: Acknowledgment letter for Distributor</u>** **3. <u>Appendix 03: FSCA and Acknowledgment letter for Healthcare Facilities</u>**
4.	4. Name/Signature	Insert Name and Title here and signature below

	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.