Effe Emme
Fabbricazioni Medicali

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Capitale Sociale € 1.800.000,00 iv.
Reg. Imprese Vercelli n. 158-3940
C.C.I.A.A. Vercelli- Rea n. 128766
Mecc. VC 007501
Cod. Fisc./P. Iva 01240770022
Cod. Ident. CEE IT01240770022

URGENT FIELD SAFETY NOTICE – FSN-01-2021
MEDICAL DEVICES – Manufacturer F.M S.p.A.

Type of Action: Stop of product usage

To the kind attention of: Distributors and final users.

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

Dear Customer,
F.M. S.p.A. is making a Field Safety Corrective Action to stop with immediate effect the usage of medical devices manufactured by F.M. S.p.A. for the codes and batches attached to the present communication.

Description of the problem.

F.M. S.p.A. has been informed by Steril Milano, one of its sterilisation suppliers, of a potential risk linked to a not correct sterilisation for some batches, because, by its own admission, some sterilisation certificates have been voluntarily and fraudulently falsified at the same sterilisation plant.
They way and the terms within which the supplier has itself denounced the illicit, in spite of ourselves, did not allow us to avoid catching and identifying any possible sterility problem before market introduction.

Following to an internal investigation, made on the information learnt from the supplier during the current month of March, F.M. S.p.A. has stated that the product sterility cannot be guaranteed.

For this reason, we ask you not to use the batches of medical devices that you have on the market and listed in the attachment A, keeping any sales on hold waiting for further notice.

Clinical impact:
The usage of non sterile medical devices in a clinical environment may lead to an increased risk of infection which may cause severe damages.
Up to now F.M. S.p.A. has not identified any notice of adverse event or serious damage to patients which might be linked to this field safety corrective action. If the product has already been used, no patient follow up activity is needed.

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Recommendation for end users:

1. Immediately stop the usage of medical devices whose batch number is present in the Attachment A
2. Use products in your warehouse whose batches are not part of the attached list.

Next steps on the customer's / distributor's side :

1. Send this field safety notice to every person internally in the organisation that have to become aware of this FSN.
2. If the product has been distributed, identify those companies and forward them immediately this notification.
3. Put into Quarantine all pieces of listed batches and complete the Customer reply form that you find on page 3. Please send it to sterilisationFSN@effeemme.it as quickly as possible and not later than 19th April 2021.

F.M. S.p.A. corrective action

F.M. S.p.A. is working to collect all needed information to evaluate which batches are really non sterile and which ones can be used because sterile.
Once the investigation is finished, in case of demonstrated sterility, F.M. S.p.A. will immediately communicate the possibility to use them. Until that moment, every batch that is part of this Attachment A cannot be used/distributed.

Contact person
In case of questions related to this letter, please contact:

sterilisationFSN@effeemme.it

We confirm that agencies and regulatory Authorities have been informed of these actions.

We want to underline that F.M. S.p.A. is committed to safety and health of every user as its first goal. We are sorry for the inconveniences that this situation may have caused but considering that these are voluntary fraudulent falsifications made by third parties unrelated to the control of F.M. S.p.A. it was not possible for us to prevent this problem.

We thank you in advance for the support that you will give us to solve this matter in the most rapid and efficient way.

Cigliano, 31st March 2021

Best regards

[redacted]

Customer and reply form

To be read together with the field safety notice **FSN-01-2021.** Send back the filled and signed form as quickly as possible and not later that 19th April 2021 to F.M. S.p.A. at the following address: sterilisationFSN@effeemme.it

☐ I confirm that the communication has been read, understood and that all recommended actions have been performed as requested.

Tick on the appropriate box here below.

☐ We DO NOT have in our possession any medical device listed in Attachment A.

☐ We have in our possession the medical devices listed in Attachment A and we confirm that the following quantities have been quarantined as stated below. (*Please note that there can be delays in the substitution production based on the product availability*).

Article	Batch number	Quarantined quantity

Name of the company:	
Dept (if applicable)	
Address:	
Postal code:	City:
Contact person:	
Role at the internal of The organisation:	Email address:
telephone number	
Signature and stamp	Date: