C.G.M. S.p.A. – Divisione Medicale META
Via E. Villa n.7 - 42124 Reggio Emilia (RE) – Italy ☎ phone +39 0522 502305 website: www.metahosp.com
info@metahosp.com

Sede Legale: Via Modena 22/24 – 42015 Correggio (RE) – Italy - P.IVA 00678290354

URGENT FIELD SAFETY NOTICE FSN-01-2021

MEDICAL DEVICES MANUFACTURED BY "CGM spa divisione medicale META"

Type of Action: STOP USING PRODUCTS

For the attention of: Distributors, Customer and Clinical staff
This letter contains important information that requires your **IMMEDIATE** attention.

Dear Customer,
CGM spa divisione medicale META is conducting a SAFETY Corrective Action in the field to immediately stop the use of CGM spa divisione medicale META branded devices, with codes and lots attached to this communication.

DESCRIPTION OF THE PRODUCT PROBLEM:
CGM spa medical division META was informed by the company STERILMILANO, one of its suppliers of the sterilization service, of a potential risk related to the incorrect sterilization of some batches as, by the supplier's own admission, some of the data of sterilization certificates have been fraudulently falsified by themselves.

Unfortunately, the methods and terms within which the supplier reported the offense, prevented us from intercepting and identifying any sterility problems before being placed on the market.
Following an internal investigation conducted on the basis of information acquired little by little from the supplier over the past few weeks, CGM spa divisione medicale META has established that the sterility of the products cannot be guaranteed.

THEREFORE, WE ASK YOU NOT TO USE THE LOTS OF MEDICAL DEVICES PRESENT ON THE MARKET AND LISTED IN ANNEX 1, KEEPING THE SALE AND / OR USE PENDING FOR FURTHER INFORMATION.

CLINICAL IMPACT:
the use of non-sterile devices in a clinical setting could lead to an increased risk of infection that can cause serious damage.
CGM spa divisione medicale META has not noticed any reports of adverse events or serious harm to patients that could be associated with this field safety corrective action. If the product has already been used, no specific patient follow-up activities are required.

ADVICE FOR CLINICAL USERS:

1) Stop the use of all devices in your possession that have the lot number listed in Annex 1
2) Use any products available in your warehouse that are not present in the list of codes and lots attached.

NEXT ACTIVITIES OF THE CUSTOMER / DISTRIBUTOR:

1) Circulate this Field Safety Notice to everyone in your organization who needs to be informed;
2) If the product has been distributed, identify these facilities and immediately submit this notification;
3) Quarantine all units of impacted batches and complete the customer response form found on page 3 and return it to .....@metahosp.com or .....@Metahosp.com as soon as possible and no later than April 30th 2021.

CORRECTIVE ACTION BY CGM spa divisione medicale META:

CGM spa divisione medicale META is working to collect all the necessary information in order to evaluate which batches are really non-sterile and which ones can instead be used as sterile.
Once the investigation is complete, if sterility is demonstrated, CGM spa divisione medicale META will promptly communicate the possibility of use.
Until that moment, all the lots listed in the annex cannot be used / distributed.

REFERENCE PERSON:

If you have any questions regarding this letter, please
contact: .....@metahosp.com
or .....@Metahosp.com

We also confirm that the notified body and the competent regulatory bodies have been informed about these actions.

We would like to inform you that CGM spa divisione medicale META aims at the safety and health of all users of its medical devices.
We apologize for all the inconveniences that this situation may cause but as these are fraudulent falsifications carried out by third parties, outside the control sphere of CGM spa divisione medicale META, it was not possible to prevent this problem.

We thank you in advance for all the support you will provide us to resolve this issue as quickly and effectively as possible.

....., April 14th 2021

C.G.M. S.p.A. – Divisione Medicale META
Via E. Villa n.7 - 42124 Reggio Emilia (RE) – Italy ☎ phone +39 0522 502305 website: www.metahosp.com
info@metahosp.com

Sede Legale: Via Modena 22/24 – 42015 Correggio (RE) – Italy - P.IVA 00678290354

CUSTOMER REPLY FORM

Read the **FSN-01-2021** safety notice and return the completed and signed form as soon as possible and no later than April 30th 2021 to CGM spa divisione medicale META at the following addresses:
.....@metahosp.com
.....@Metahosp.com

☐ **I CONFIRM THAT THIS NOTICE HAS BEEN READ, UNDERSTAND AND THAT ALL RECOMMENDED ACTIONS HAVE BEEN IMPLEMENTED AS REQUIRED**.

Additionally, we ask you to tick the following appropriate box:

☐ We do NOT have any of the devices listed in Annex 1 in our possession

☐ We have in our possession the medical device units listed in Annex 1 and we confirm that the Following units, as indicated below, have been quarantined and will NOT be used:

REF	BATCH /LOT	QUANTITY PLACED IN QUARANTINE

Company/Facility name:	
Department (if applicable):	
Adress:	
Postal Code:	
Contact Name:	
Professional role in the company:	
Contact email address:	
Contact phone number:	
Signature and stamp:	Date: