Safety Communication رسالة سلامة

Deviations of sterilization process parameters

Device/ Product Description:	Injections / Infusions / Transfusions / Dialysis - catheters	
Affected product:	**Check the attached "Field Safety Notice" Here.**	
Manufacturer:	Delta Med spa	
Problem:	The above mentioned product are supplied to the market in sterile status, following the Ethylene Oxide sterilization process performed overtime by sterilization service providers (Steril Milano Srl). Possible deviations of sterilization process parameters (in specific Lots/Batches) required the legal manufacturer to conduct a Field Safety Corrective Action (FSCA).	
Recommendation /Actions:	• Make sure that this document is reached to the end-users. • Go through the links above to find out all the details and instructions. • Identify and quarantine any affected products. • Contact the authorized representative mentioned in the links above for the required support. If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system (19999) unified call center	
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