Safety Communication رسالة سلامة

Deviations of sterilization process parameters

Device/ Product Description:	Prismaflex Sets	
Affected product:	**Check the attached "Field Safety Notice" Here.**	
Manufacturer:	Baxter Healthcare	
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 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	
	AR name:	Baxter AG

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