Safety Communication رسالة سلامة

Deviations of sterilization process parameters

Device Name/Description	Manufacturer	Link
Urogenital surgical laser system beam guide	Quanta System SpA	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=8&rid=15666
Covidien DAR airway products	Covidien LLC	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15673
Insufflation Filter	KARL STORZ SE & Co. KG	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15671
Medication Delivery	Baxter AG	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15669
Contact lens solutions	Bausch & Lomb GmbH.	https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15676
Problem:	The above mentioned products 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 manufacturers 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	