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قطاع الأجهزة والمستلزمات الطبية
المركز الوطني لبلاغات الأجهزة والمستلزمات الطبية

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Medical Devices Sector
National Center for Medical Devices Reporting

Safety Communication
رسالة سلامة

To: Healthcare Providers	**إلى:** مقدمي الرعاية الصحية

Title:	A Potential risk of Infections Associated with Reprocessed Duodenoscopes	**العنوان:**
Medical Device Description:	All Reusable Duodenoscopes	**اسم ووصف الجهاز/المستلزم الطبي:**
Medical Device Products Identifier:	All	**الأرقام للجهاز/المستلزم الطبي:**
Manufacturer:	All Manufacturers for Reusable duodenoscopes	**اسم المصنع:**
Authorized Representative:	All Authorized Representative for Reusable duodenoscopes	**الممثل المعتمد:**

Medical Devices Marketing Authorization (MDMA):	All MDMA for Reusable duodenoscopes	**إذن التسويق:**
Potential /Associated risks:	Detection of contamination after performing sterilization for duodenoscopes.	**المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي:**
Recommendations:	Recommendations for healthcare providers: - Develop a process to ensure that reprocessing employees follow the manufacturer's IFU and take appropriate action when deviations occur (ex.: duodenoscope quarantine, extra reprocessing, retraining reprocessing employees). - Before acquiring a new duodenoscope, make sure the reprocessing capabilities of the healthcare facility are compatible with the duodenoscope technology.	**التوصيات:**
For Reporting:	SFDA 19999 مركز الاتصال الموحد · NCMDR · Saudi Vigilance يقظ	**للإبلاغ:**