

Date: 11/6/2022

Reference Number: SG-2211-400-H

قطاع الأجهزة والمستلزمات الطبية المركز الوطني لبلاغات الأجهزة والمستلزمات الطبية

Medical Devices Sector National Center for Medical Devices Reporting الهيئت الصامت للضذاء والدواء Saudi Food & Drug Authority

## رسالة سلامة Safety Communication

To: Healthcare Providence	ders	ن: مقدمي الرعاية الصد
Title	Risk of Bacterial Contamination	العنوان
Medical Device Description	Ultrasound Gel Products	اسم ووصف جهاز/المستلزم الطبي
Medical Device Products Identifier	All	أرقام للجهاز/المستلزم الطبي
Manufacturer	All	اسم المصنع
Authorized Representative	All	الممثل المعتمد
Medical Devices Marketing Authorization (MDMA)	All	إذن التسويق
Potential /Associated risks:	Contaminated ultrasound gel has been associated with infection outbreaks in various settings and identified as a potential vector for infection.	المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي
Recommendations	<ul> <li>Healthcare providers must follow the intended uses of ultrasound gel according to the manufacturer's recommendations.</li> <li>Healthcare providers must store the ultrasound gel according to the manufacturer's recommendations in an area that is dry and away from potential sources of contamination and dispose of the container if it appears soiled, damaged, or is out of date.</li> <li>Healthcare providers must have a policy and procedure for good infection prevention practice of ultrasound gel products.</li> <li>Healthcare providers must ensure that healthcare workers carry out hand hygiene before and after the use of ultrasound gel.</li> <li>Healthcare providers must check the expiration date on ultrasound gel bottles before using them.</li> </ul>	المتوصيات
For Reporting	SFDA 19999 NCMDR فركر الانصال الموحد Saudi Viciliance	للإبلاغ:

Code: MDS-F-310-020-V4