Safety Communication رسالة سلامة

Potential risk when using the system with specific software versions

Device/ Product Description:	In-vitro diagnostics - microbiological products	
Affected product:	Model Name:	Accelerate Pheno system.
	Catalogue No.:	10401008, 10301008
Manufacturer:	Accelerate Diagnostics Inc	
Problem:	Potential risk of very major discrepancies, major discrepancies and/or essential agreement <90% with some organism-antimicrobial combinations as listed below, when using the Accelerate Pheno™ system with software versions 1.4.1 and later.	
Recommendation /Actions:	• Make sure that this document is reached to the end-users. • Follow the instructions as indicated in the attached Field Safety Corrective Action. • Contact the authorized representative for required corrective action. For more information please click here. 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	

Devices/Products photo:		
Authorized Representative Details	AR name:	Creative Healthcare Establishment
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