

Safety Communication

رسالة سلامة

QUADROX-iD Pediatric with BIOLINE Coating may be compromised during transportation

Device/ Product Description:	QUADROX-iD Pediatric with BIOLINE Coating
Details on affected devices:	Model Number: BE-HMOD 30000 Part Number: 701047041 Lot Numbers: 70124702, 70120467, 70121343, 70122531, 70125287, 70130805, 70124701, 70119853, 70123312, 70122267, 70123904, 70121443, 70119850, 70121443, 70119850 and 70123493
Manufacturer:	MAQUET Cardiopulmonary GmbH
Problem:	Maquet Cardiopulmonary has determined that the sterile barrier system of the QUADROX-iD Pediatric oxygenator may be compromised during transportation. Under unfavorable transport conditions, excessive movement of the device and its accessories in the carton can lead to stress points that could compromise the sterile barrier of the packaging pouches. Tests revealed that the primary packaging of the QUADROX-iD Pediatric might be breached. The size of the breach is small, which may be difficult for the user to detect.
Recommendation/Actions:	Customers are advised to immediately inspect stock for the affected product lot numbers and quarantine. Please return immediately all affected products in your stock. For more information Please click here

Devices/Products photo:



**Authorized Representative
Details**

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