

تعميم رقم (50 / 2026) Circular No.

Date: 16/03/2026

التاريخ: 16/03/2026

To:
Healthcare & Pharmaceutical Facilities
Healthcare Professionals

إلى:
منشآت الرعاية الصحية والصيدلانية
المهنيين الصحيين

Subject: Medical Devices Field Safety Alert

الموضوع: إشعار السلامة لعدد من الوسائل الطبية

We extend our greetings and best wishes for your continued success.

بدايةً، يسرنا أن نتقدم لكم بخالص التحية والتقدير متمنين لكم دوام التوفيق والسداد.

The Department of Health (DoH) would like to bring to your attention the circular issued by the Emirates Drug Establishment (EDE) on the following Medical Devices Field Safety Alert:

تلقت دائرة الصحة انتباهكم جميعاً إلى التعميم الصادر من مؤسسة الإمارات للدواء بشأن تقارير السلامة للوسائل الطبية التالية:

Medical device	Manufacturer	Classification
Anesthetic and respiratory devices		
AquaVENT® NeoFlow® nCPAP System, AquaVENT® NeoFlow® Humidified Oxygen System, AquaVENT® NeoFlow® Heated Ventilator Circuit	Armstrong Medical Ltd.	Recall
FlurAbsorb Pro-S and FlurAbsorb Pro-L	Sedana Medical AB	Safety notification
Treadmill locomotion 150/50 DE med and locomotion 190/65 DE med	h/p/cosmos sports & medical gmbh.	Safety notification
Diagnostic and therapeutic radiation devices		
FDR Visionary Suite	FUJIFILM Medical Systems	Recall

التصنيف	الشركة المصنعة	الوسيلة الطبية
أجهزة التخدير والجهاز التنفسي		
Recall	Armstrong Medical Ltd.	AquaVENT® NeoFlow® nCPAP System, AquaVENT® NeoFlow® Humidified Oxygen System, AquaVENT® NeoFlow® Heated Ventilator Circuit
Safety notification	Sedana Medical AB	FlurAbsorb Pro-S and FlurAbsorb Pro-L
Safety notification	h/p/cosmos sports & medical gmbh.	Treadmill locomotion 150/50 DE med and locomotion 190/65 DE med
أجهزة الإشعاع التشخيصي والعلاجي		
Recall	FUJIFILM Medical Systems	FDR Visionary Suite

Focalyx Fusion	Focalyx Technologies, LLC.	Recall
Ingenia	Philips Medical Systems	Recall
Leksell Gamma Knife	Elekta Inc	Product Correction
Philips Allura and Azurion systems	Philips Healthcare	Safety notification
SOMATOM X.ceed	Siemens Healthcare GmbH	Recall
Electromechanical medical devices		
CADD High Volume Administration Sets	ICU Medical, Inc	Safety notification
D Alaris™ neXus and Alaris™ Plus Syringe Pumps	BD (Becton Dickinson)	Safety notification
da Vinci X, Xi Surgical System, & da Vinci 5 Surgical System	Intuitive Surgical Inc	Recall
MiniMed 780G Insulin Pump	Medtronic MiniMed...	Recall
Nutricia Flocare Infinity III Enteral Feeding Pump	Nutricia Medical Devices	Product Correction
IMMULITE 2000 EPO & IMMULITE EPO Control Module	Siemens Healthcare Diagnostics Inc.	Product Correction
Kangaroo Power Cord and Enteral Feeding Pumps	Cardinal Health 200, LLC..	Product Correction
Olympus High Flow Insufflation Unit and UHI-3 INSUFFLATOR BUILT-IN SMOKE EVAC	Olympus Europa SE & CO.KG..	Recall
Tentos 4F	Optimed Medizinische Instrumente GmbH..	Recall
Hospital hardware		
Laerdal Compact Suction Unit 4	Laerdal Medical AS.	Recall

Recall	Focalyx Technologies, LLC.	Focalyx Fusion
Recall	Philips Medical Systems	Ingenia
Product Correction	Elekta Inc	Leksell Gamma Knife
Safety notification	Philips Healthcare	Philips Allura and Azurion systems
Recall	Siemens Healthcare GmbH	SOMATOM X.ceed
الأجهزة الطبية الكهروميكانيكية		
Safety notification	ICU Medical, Inc	CADD High Volume Administration Sets
Safety notification	BD (Becton Dickinson)	D Alaris™ neXus and Alaris™ Plus Syringe Pumps
Recall	Intuitive Surgical Inc	da Vinci X, Xi Surgical System, & da Vinci 5 Surgical System
Recall	Medtronic MiniMed...	MiniMed 780G Insulin Pump
Product Correction	Nutricia Medical Devices	Nutricia Flocare Infinity III Enteral Feeding Pump
Product Correction	Siemens Healthcare Diagnostics Inc.	IMMULITE 2000 EPO & IMMULITE EPO Control Module
Product Correction	Cardinal Health 200, LLC..	Kangaroo Power Cord and Enteral Feeding Pumps
Recall	Olympus Europa SE & CO.KG..	Olympus High Flow Insufflation Unit and UHI-3 INSUFFLATOR BUILT-IN SMOKE EVAC
Recall	Optimed Medizinische Instrumente GmbH..	Tentos 4F
معدات المستشفيات		
Recall	Laerdal Medical AS.	Laerdal Compact Suction Unit 4

TU2000 TRYTABLE	MEDKONSULT medical technology s.r.o..	Discontinuation of the product
In vitro diagnostic devices		
Actim® PROM Ingeni Test (30832RETAL)	Actim Oy.	Recall
COULTER DxH Diluent	Beckman Coulter...	Recall
Exploro Highly Sensitive Male Fertility / Sperm Concentration Test	Changchun Wancheng Bio-Electron Co., Ltd.	Recall
GEM PAKs for GEM Premier 5000 with iQM2	Instrumentation Laboratory SpA, a Werfen Company	Recall
Lumipulse G pTau217/B-Amyloid 1-42 Plasma Ratio	Fujirebio Diagnostics, Inc.	Recall
NucleoSpin® Dx Blood	Macherey Nagel Gmbh & Co. Kg	Recall
STA Liatest D-Di Plus	Diagnostica Stago S.A.S.	Safety notification
STA LIATEST FREE PROTEIN S 6 and STA LIATEST FREE PROTEIN S 2	Diagnostica Stago	Removal
VITROS Immunodiagnostic Products Progesterone 2 Calibrators and Reagent Pack	Ortho-Clinical Diagnostics	Product Correction
Laboratory equipment		
VITROS 4600 Chemistry System - VITROS 5600 Integrated System - VITROS XT 7600 Integrated System	Ortho-Clinical Diagnostics	Product Correction
Non-active Implantable Devices		
A TEC Lateral Navigation Disc Prep Instruments	Alphatec Spine Inc	Recall

Discontinuation of the product	MEDKONSULT medical technology s.r.o..	TU2000 TRYTABLE
أجهزة التشخيص المخبري		
Recall	Actim Oy.	Actim® PROM Ingeni Test (30832RETAL)
Recall	Beckman Coulter...	COULTER DxH Diluent
Recall	Changchun Wancheng Bio-Electron Co., Ltd.	Exploro Highly Sensitive Male Fertility / Sperm Concentration Test
Recall	Instrumentation Laboratory SpA, a Werfen Company	GEM PAKs for GEM Premier 5000 with iQM2
Recall	Fujirebio Diagnostics, Inc.	Lumipulse G pTau217/B-Amyloid 1-42 Plasma Ratio
Recall	Macherey Nagel Gmbh & Co. Kg	NucleoSpin® Dx Blood
Safety notification	Diagnostica Stago S.A.S.	STA Liatest D-Di Plus
Removal	Diagnostica Stago	STA LIATEST FREE PROTEIN S 6 and STA LIATEST FREE PROTEIN S 2
Product Correction	Ortho-Clinical Diagnostics	VITROS Immunodiagnostic Products Progesterone 2 Calibrators and Reagent Pack
معدات المختبر		
Product Correction	Ortho-Clinical Diagnostics	VITROS 4600 Chemistry System - VITROS 5600 Integrated System - VITROS XT 7600 Integrated System
الأجهزة المزروعة الغير نشطة		
Recall	Alphatec Spine Inc	A TEC Lateral Navigation Disc Prep Instruments

Drive Mechanism	OrthoPediatics Corp	Recall
EMPOWR Dual Mobility	Encore Medical, L.P..	Recall
Ergo Impactor Handle	Exactech	Recall
Exactech Equinox Reverse Total Shoulder Arthroplasty System	Exatech inc.	Product Alert
H3 Hintermann Ankle Replacemen System	DT MedTech	Product Alert
TORNIER PERFORM REVERSED PERIP SCREW	Tornier Inc..	Recall
Reusable devices		
Cystoscope Outer sheath, 22.5 Fr.	Olympus Europa SE & CO.KG..	Recall
Single-use devices		
AquaUltra Clear	Ultragel 2000 Hungary Kft	Recall
AXIOS™ Stent and Electrocautery Enhanced Delivery Systems	Boston Scientific Corp..	Recall
Basic Endotracheal Tube	Multigate Medical Products. Pty Ltd.	Product Correction
Clinell Universal Wipes	GAMA Healthcare Ltd.	Recall
Darcofoam	Dr. Ausbüttel & Co. GmbH	Recall
Extra-Corporeal Circuit Tube	Tianjin Plastics Research Institute Co., Ltd.	Recall
Halyard TRANSPORT BAG KIT. Kit Code: LIFE0080-01.	Avid Medical, Inc.	Recall
Intubation Tray and Suction Catheter.	Medline Industries Inc	Recall
LimFlow Vector	LimFlow, Inc.	Recall

Recall	OrthoPediatics Corp	Drive Mechanism
Recall	Encore Medical, L.P..	EMPOWR Dual Mobility
Recall	Exactech	Ergo Impactor Handle
Product Alert	Exatech inc.	Exactech Equinox Reverse Total Shoulder Arthroplasty System
Product Alert	DT MedTech	H3 Hintermann Ankle Replacemen System
Recall	Tornier Inc..	TORNIER PERFORM REVERSED PERIP SCREW
أجهزة قابلة لإعادة الاستخدام		
Recall	Olympus Europa SE & CO.KG..	Cystoscope Outer sheath, 22.5 Fr.
الأجهزة ذات الاستعمال الواحد		
Recall	Ultragel 2000 Hungary Kft	AquaUltra Clear
Recall	Boston Scientific Corp..	AXIOS™ Stent and Electrocautery Enhanced Delivery Systems
Product Correction	Multigate Medical Products. Pty Ltd.	Basic Endotracheal Tube
Recall	GAMA Healthcare Ltd.	Clinell Universal Wipes
Recall	Dr. Ausbüttel & Co. GmbH	Darcofoam
Recall	Tianjin Plastics Research Institute Co., Ltd.	Extra-Corporeal Circuit Tube
Recall	Avid Medical, Inc.	Halyard TRANSPORT BAG KIT. Kit Code: LIFE0080-01.
Recall	Medline Industries Inc	Intubation Tray and Suction Catheter.
Recall	LimFlow, Inc.	LimFlow Vector

LSL Healthcare, Central Line Dressing Kit	LSL Healthcre Inc.	Recall
MAJ-210 Single Biopsy Valve	Olympus Corporation of the Americas .	Product Alert
Medline ReNewal Reprocessed ViewFlex Xtra ICE Catheter, Medline ReNewal Reprocessed Abbott Inquiry Steerable Diagnostic Catheter, Medline ReNewal Reprocessed BW Webster CS Catheter with EZ Steer Technology; and Auto ID Technology, Medline ReNewal Reproces	Medline Industries Inc	Recall
OLYMPUS CleverCut and FlowCut Sphincterotomes	Olympus Corporation of the Americas.	Recall
Vortex Surgical Kit, Volk, Tecfen, Oertli and Rumex.	Vortex Surgical Inc	Recall

Recall	LSL Healthcre Inc.	LSL Healthcare, Central Line Dressing Kit
Product Alert	Olympus Corporation of the Americas .	MAJ-210 Single Biopsy Valve
Recall	Medline Industries Inc	Medline ReNewal Reprocessed ViewFlex Xtra ICE Catheter, Medline ReNewal Reprocessed Abbott Inquiry Steerable Diagnostic Catheter, Medline ReNewal Reprocessed BW Webster CS Catheter with EZ Steer Technology; and Auto ID Technology, Medline ReNewal Reproces
Recall	Olympus Corporation of the Americas.	OLYMPUS CleverCut and FlowCut Sphincterotomes
Recall	Vortex Surgical Inc	Vortex Surgical Kit, Volk, Tecfen, Oertli and Rumex.

Based on the above, the DoH requires the following actions to be taken:

1. The manufacturing companies shall provide the (FSN/FSCA) of the above-mentioned medical devices to the users.
2. Healthcare professionals must:
 - Follow the instructions listed in the links included in the attached document, as provided by the manufacturers.

بناءً على ذلك، فإن دائرة الصحة تطالب باتخاذ

الإجراءات التالية:

1. على الشركات المُصنِّعة توفير تقارير السلامة (FSN/FSCA) للوسائل الطبية المذكورة أعلاه للمستخدمين.

2. على المهنيين الصحيين:

- اتباع التعليمات الموضحة في الروابط المدرجة في المستند المرفق والتي تم توفيرها من قبل الشركات المُصنِّعة.



- Report any adverse events associated with the use of medical products to our Pharmacovigilance program through the online e-notification system:

<https://www.doh.gov.ae/en/resources/Reporting>

Contact Details:

Pharmacovigilance program via email:

PVE@doh.gov.ae

Your cooperation in implementing these measures is essential for ensuring patient safety and maintaining the quality of healthcare services in the Emirate of Abu Dhabi.

Thank you for your prompt attention to this matter.

This circular is designed for regulatory procedures and should not be used as content for media publication

- الإبلاغ عن حدوث أي آثار جانبية ناجمة عن استخدام المنتجات الطبية إلى برنامج اليقظة الدوائية عبر نظام التبليغ الإلكتروني:

<https://www.doh.gov.ae/en/resources/Reporting>

بيانات التواصل:

برنامج اليقظة الدوائية عبر البريد الإلكتروني:

PVE@doh.gov.ae

تعاونكم في تنفيذ هذه الإجراءات ضروري لضمان سلامة المرضى والحفاظ على جودة الخدمات الصحية في إمارة أبوظبي.

شاكرين لكم حسن تعاونكم معنا،

هذا التعميم مخصص للإجراءات التنظيمية وغير مخصص كمحتوى للنشر الإعلاني



د. نورة خميس الغيثي

وكيل دائرة الصحة





Field Safety Corrective Actions:

Medical device	Manufacturer	Classification	Link
Anaesthetic and respiratory devices			
AquaVENT® NeoFlow® nCPAP System, AquaVENT® NeoFlow® Humidified Oxygen System, AquaVENT® NeoFlow® Heated Ventilator Circuit	Armstrong Medical Ltd.	Recall	Microsoft Word - FSN Nasal Cannula Connector Adaptor Jan 2026.docx
FlurAbsorb Pro-S and FlurAbsorb Pro-L	Sedana Medical AB	Safety notification	06449-26_kundeninfo_en.pdf
Treadmill locomotion 150/50 DE med and locomotion 190/65 DE med	h/p/cosmos sports & medical gmbh.	Safety notification	Microsoft Word - 20260119 FSN FSCA_VF2026-0003_hpcosmos_magnetic_ripcord_reissleine_cos101418-02_EN.docx
Diagnostic and therapeutic radiation devices			
FDR Visionary Suite	FUJIFILM Medical Systems	Recall	Class 2 Device Recall FDR Visionary Suite
Focalyx Fusion	Focalyx Technologies, LLC.	Recall	Class 2 Device Recall SmartTarget
Ingenia	Philips Medical Systems	Recall	Class 2 Device Recall Philips
Leksell Gamma Knife	Elekta Inc	Product Correction	Database of Recalls, Product Alerts and Product Corrections - details
Philips Allura and Azurion systems	Philips Healthcare	Safety notification	https://ade.sfda.gov.sa/Fsca/PublishDetails/263
SOMATOM X.ceed	Siemens Healthcare GmbH	Recall	Class 2 Device Recall SOMATOM X.ceed
Electro mechanical medical devices			
CADD High Volume Administration Sets	ICU Medical, Inc	Safety notification	06509-26_kundeninfo_en.pdf
D Alaris™ neXus and Alaris™ Plus Syringe Pumps	BD (Becton Dickinson)	Safety notification	OneDrive
da Vinci X, Xi Surgical System, & da Vinci 5 Surgical System	Intuitive Surgical Inc	Recall	Class 2 Device Recall Da Vinci
MiniMed 780G Insulin Pump	Medtronic MiniMed...	Recall	Class 2 Device Recall MiniMed 780G
Nutricia Flocare Infinity III Enteral Feeding Pump	Nutricia Medical Devices	Product Correction	Database of Recalls, Product Alerts and Product Corrections - details
IMMULITE 2000 EPO & IMMULITE EPO Control Module	Siemens Healthcare Diagnostics Inc.	Product Correction	Database of Recalls, Product Alerts and Product Corrections - details





Field Safety Corrective Actions:

Kangaroo Power Cord and Enteral Feeding Pumps	Cardinal Health 200, LLC..	Product Correction	Database of Recalls, Product Alerts and Product Corrections - details
Olympus High Flow Insufflation Unit and UHI-3 INSUFFLATOR BUILT-IN SMOKE EVAC	Olympus Europa SE & CO.KG..	Recall	Database of Recalls, Product Alerts and Product Corrections - details
Tentos 4F	optimed Medizinische Instrumente GmbH..	Recall	59170-25_kundeninfo_en.pdf
Hospital hardware			
Laerdal Compact Suction Unit 4	Laerdal Medical AS.	Recall	Class 2 Device Recall LAERDAL COMPACT SUCTION UNIT
TU2000 TRYTABLE	MEDKONSULT medical technology s.r.o..	Discontinuation of the product	04751-26_kundeninfo_en.pdf
In vitro diagnostic devices			
Actim® PROM 1ngeni Test (30832RETAL)	Actim Oy.	Recall	05193-26_kundeninfo_en.pdf
COULTER DxH Diluent	Beckman Coulter...	Recall	Class 2 Device Recall COULTER DxH Diluent DxH ECO Diluent
Exploro Highly Sensitive Male Fertility / Sperm Concentration Test	Changchun Wancheng Bio-Electron Co., Ltd.	Recall	Class 2 Device Recall Exploro Highly Sensitive Male Fertility / Sperm Concentration Test
GEM PAKs for GEM Premier 5000 with iQM2	Instrumentation Laboratory SpA, a Werfen Company	Recall	Database of Recalls, Product Alerts and Product Corrections - details
Lumipulse G pTau217/B-Amyloid 1-42 Plasma Ratio	Fujirebio Diagnostics, Inc.	Recall	Class 2 Device Recall Lumipulse G pTau217/BAmyloid 142 Plasma Ratio
NucleoSpin® Dx Blood	Macherey Nagel GmbH & Co. Kg	Recall	03316-26_kundeninfo_en.pdf
STA Liatest D-Di Plus	Diagnostica Stago S.A.S.	Safety notification	https://ade.sfda.gov.sa/Fsca/PublishDetails/725
STA LIATEST FREE PROTEIN S 6 and STA LIATEST FREE PROTEIN S 2	Diagnostica Stago	Removal	https://ade.sfda.gov.sa/Fsca/PublishDetails/719
VITROS Immunodiagnostic Products Progesterone 2 Calibrators and Reagent Pack	Ortho-Clinical Diagnostics	Product Correction	Database of Recalls, Product Alerts and Product Corrections - details
Laboratory equipment			
VITROS 4600 Chemistry System - VITROS 5600 Integrated System - VITROS XT 7600 Integrated System	Ortho-Clinical Diagnostics	Product Correction	Database of Recalls, Product Alerts and Product Corrections - details
Non-active Implantable Devices			





Field Safety Corrective Actions:

ATEC Lateral Navigation Disc Prep Instruments	Alphatec Spine Inc	Recall	Class 2 Device Recall ATEC Lateral Navigation Disc Prep Instruments
Drive Mechanism	OrthoPediatrics Corp	Recall	03823-26_kundeninfo_en.pdf
EMPOWR Dual Mobility	Encore Medical, L.P..	Recall	Class 2 Device Recall EMPOWR 3D Knee Tibial Insert
Ergo Impactor Handle	Exactech	Recall	03626-26_kundeninfo_en.pdf
Exactech Equinoxe Reverse Total Shoulder Arthroplasty System	Exatech inc.	Product Alert	Database of Recalls, Product Alerts and Product Corrections - details
H3 Hintermann Ankle Replacemen System	DT MedTech	Product Alert	Database of Recalls, Product Alerts and Product Corrections - details
TORNIER PERFORM REVERSED PERIP SCREW	Tornier Inc..	Recall	Class 2 Device Recall Tornier Perform Reversed Glenoid
Reusable devices			
Cystoscope Outer sheath, 22.5 Fr.	Olympus Europa SE & CO.KG..	Recall	02617-26_kundeninfo_en.pdf
Single-use devices			
AquaUltra Clear	Ultragel 2000 Hungary Kft	Recall	03749-26_kundeninfo_en.pdf
AXIOS™ Stent and Electrocautery Enhanced Delivery Systems	Boston Scientific Corp..	Recall	Class 1 Device Recall AXIOS Stent and ElectrocauteryEnhanced Delivery System
Basic Endotracheal Tube	Multigate Medical Products. Pty Ltd.	Product Correction	Database of Recalls, Product Alerts and Product Corrections - details
Clinell Universal Wipes	GAMA Healthcare Ltd.	Recall	Database of Recalls, Product Alerts and Product Corrections - details
Darcofoam	Dr. Ausbüttel & Co. GmbH	Recall	04537-26_kundeninfo_en.pdf
Extra-Corporeal Circuit Tube	Tianjin Plastics Research Institute Co., Ltd.	Recall	06050-26_kundeninfo_en.pdf
Halyard TRANSPORT BAG KIT. Kit Code: LIFE0080-01.	Avid Medical, Inc.	Recall	Class 2 Device Recall Halyard
Intubation Tray and Suction Catheter.	Medline Industries Inc	Recall	Class 2 Device Recall Medline
LimFlow Vector	LimFlow, Inc.	Recall	Class 2 Device Recall LimFlow Vector
LSL Healthcare, Central Line Dressing Kit	LSL Healthcre Inc.	Recall	Class 2 Device Recall LSL Healthcare
MAJ-210 Single Biopsy Valve	Olympus Corporation of the Americas .	Product Alert	Database of Recalls, Product Alerts and Product Corrections - details





Field Safety Corrective Actions:

Medline ReNewal Reprocessed ViewFlex Xtra ICE Catheter, Medline ReNewal Reprocessed Abbott Inquiry Steerable Diagnostic Catheter, Medline ReNewal Reprocessed BW Webster CS Catheter with EZ Steer Technology; and Auto ID Technology, Medline ReNewal Reproces	Medline Industries Inc	Recall	Class 1 Device Recall Abbott Inquiry Steerable Diagnostic Catheter
OLYMPUS CleverCut and FlowCut Sphincterotomes	Olympus Corporation of the Americas .	Recall	Class 2 Device Recall Disposable Triple Lumen Sphincterotome
Vortex Surgical Kit, Volk, Tecfen, Oertli and Rumex.	Vortex Surgical Inc	Recall	Class 2 Device Recall Vortex Surgical

