Circular No.(2026 / 133) تعميـم رقم

Date: 21/07/2026

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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، يسرّنا 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:

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

Medical device	Manufacturer	Classification
Active Implantable Devices		
Intera Oncology INTERA 3000 Hepatic Artery Infusion Pump, AP-0300H	Boston Scientific Corp..	Recall
Anaesthetic and respiratory devices		
Astral 100/150	ResMed Limited.	Product Correction
Hillrom VOLARA System	Hill Rom Inc	Recall
LEONI plus / LEONI plus HFO / LEONI plus transport ventilators	Lowenstein Medical GmbH &Co.KG	Product Correction
Assistive products for persons with disability		
E-motion M25 Wheels	Alber GmbH	Product Correction
Winn'Motion 150 & 175 patient lift.	WINNCARE Spain	Product Correction
Cardiovascular Devices		

التصنيف	الشركة المصنعة	الوسيلة الطبية
أجهزة الزرع النشطة		
Recall	Boston Scientific Corp..	Intera Oncology INTERA 3000 Hepatic Artery Infusion Pump, AP-0300H
أجهزة التخدير والجهاز التنفسي		
Product Correction	ResMed Limited.	Astral 100/150
Recall	Hill Rom Inc	Hillrom VOLARA System
Product Correction	Lowenstein Medical GmbH &Co.KG	LEONI plus / LEONI plus HFO / LEONI plus transport ventilators
المنتجات المساعدة ألصحاب الهمم		
Product Correction	Alber GmbH	E-motion M25 Wheels
Product Correction	WINNCARE Spain	Winn'Motion 150 & 175 patient lift.
أجهزة القلب والأوعية الدموية		

NephroMax™ High Pressure Nephrostomy Balloon Catheters (multiple variants)	Boston Scientific International S.A., Voisins le Bretonneux, France	Product Correction
Diagnostic and therapeutic radiation devices		
CyberKnife® System with XChange Robotic Collimator Changer	Accuray Incorporated	Product Correction
MR systems with SW versions R11.1 and R12.1	Philips Healthcare	Product Correction
Philips Allura R8.2 systems	Philips Medical Systems Nederland B.V.	Product Correction
Philips Azurion and Allura Systems	Philips Medical Systems Nederland B.V.	Product Correction
Electro mechanical medical devices		
Omnipod DASH® Insulin Management System	Insulet Corporation.	Recall
Philips Avalon Fetal Monitor	Philips Healthcare	Product Correction
ROSA ONE Brain Application	Zimmer Biomet	Product Correction
Hospital hardware		
HKH 8820 Wall Holder	MAQUET Cardiopulmonary GmbH	Product Correction
In vitro diagnostic devices		
GC Agar Base (150mm) 10/PK R04030, GC Agar Base (100mm) 10/PK R01460	Remel Inc.	Recall
GLP systems Track Centrifuge Module (CM)	Abbott Automation Solutions GmbH, Hamburg, Germany (Core Diagnostics)	Product Correction
Oncomine DX Express Test Panel	Thermo Fisher Scientific Oy	Product Correction
The RIDAPlex Respiratory Pathogens C 16 well Step 1	AusDiagnostics Pty Ltd	Recall
Medical software		

Product Correction	Boston Scientific International S.A., Voisins le Bretonneux, France	NephroMax™ High Pressure Nephrostomy Balloon Catheters (multiple variants)
أجهزة الإشعاع التشخيصي والعلاجي		
Product Correction	Accuray Incorporated	CyberKnife® System with XChange Robotic Collimator Changer
Product Correction	Philips Healthcare	MR systems with SW versions R11.1 and R12.1
Product Correction	Philips Medical Systems Nederland B.V.	Philips Allura R8.2 systems
Product Correction	Philips Medical Systems Nederland B.V.	Philips Azurion and Allura Systems
الأجهزة الطبية الكهروميكانيكية		
Recall	Insulet Corporation.	Omnipod DASH® Insulin Management System
Product Correction	Philips Healthcare	Philips Avalon Fetal Monitor
Product Correction	Zimmer Biomet	ROSA ONE Brain Application
معدات المستشفيات		
Product Correction	MAQUET Cardiopulmonary GmbH	HKH 8820 Wall Holder
أجهزة التشخيص المخبري		
Recall	Remel Inc.	GC Agar Base (150mm) 10/PK R04030, GC Agar Base (100mm) 10/PK R01460
Product Correction	Abbott Automation Solutions GmbH, Hamburg, Germany (Core Diagnostics)	GLP systems Track Centrifuge Module (CM)
Product Correction	Thermo Fisher Scientific Oy	Oncomine DX Express Test Panel
Recall	AusDiagnostics Pty Ltd	The RIDAPlex Respiratory Pathogens C 16 well Step 1
البرامج الطبية		

Atrio v5.0.1 and Atrio Plus v1.1.0 - 2.0.0	Alerte Digital Health Pte Ltd	Product Correction
RayCare 2024A SP1 RayCare 2024A SP4	RaySearch Laboratories AB (publ)	Recall
Non-active implantable devices		
Depuy Synthes, ATTUNE Revision Hinge Knee Hinge Insert Components	DePuy International Limited	Recall
Mariner Polyaxial Head components used within the Mariner Pedicle Screw System	SeaSpine Orthopedics Corporation.	Recall
Phantom Hindfoot TCC/TC Ball Tipped Guide Rod 3.0 x 800mm Sterile	Paragon 28, Inc..	Recall
Short Monobloc Stem Broaches.	Medacta International SA,	Recall
Single-use device		
10ml Syringe LuerLok Tip	Mentor Texas LP	Recall
A M S, ALIGNED MEDICAL SOLUTIONS surgical convenience kit	Windstone Medical Packaging, Inc..	Recall
BLEPHADEMODEX	Laboratories THEA S.A.S	Product Correction
Climber Guiding Catheter 6F 3.5EBU shape	PendraCare International B.V...	Recall
ConvaVAC™ NPWT Dressings	ConvaTec.	Product Correction
Convenience kits	Medline Industries Inc	Recall
Convenience Kits	Medline Industries Inc	Recall
Custom Tubing Packs (CTPs)	MAQUET Cardiopulmonary GmbH	Recall
ENFit ExSet Strl 60 2.0ml PV 1ct EN	Medela INC....	Recall
EOPA 3D Arterial Cannulae and EOPA Elongated One-Piece Arterial Cannulae	Medtronic Inc.	Recall
Impella Set with smart assist Introducer Kit for Impella CP	ABIOMED Inc	Recall

Product Correction	Alerte Digital Health Pte Ltd	Atrio v5.0.1 and Atrio Plus v1.1.0 - 2.0.0
Recall	RaySearch Laboratories AB (publ)	RayCare 2024A SP1 RayCare 2024A SP4
الأجهزة المزروعة الغير نشطة		
Recall	DePuy International Limited	Depuy Synthes, ATTUNE Revision Hinge Knee Hinge Insert Components
Recall	SeaSpine Orthopedics Corporation.	Mariner Polyaxial Head components used within the Mariner Pedicle Screw System
Recall	Paragon 28, Inc..	Phantom Hindfoot TCC/TC Ball Tipped Guide Rod 3.0 x 800mm Sterile
Recall	Medacta International SA,	Short Monobloc Stem Broaches.
الأجهزة ذات الاستعمال الواحد		
Recall	Mentor Texas LP	10ml Syringe LuerLok Tip
Recall	Windstone Medical Packaging, Inc..	A M S, ALIGNED MEDICAL SOLUTIONS surgical convenience kit
Product Correction	Laboratories THEA S.A.S	BLEPHADEMODEX
Recall	PendraCare International B.V...	Climber Guiding Catheter 6F 3.5EBU shape
Product Correction	ConvaTec.	ConvaVAC™ NPWT Dressings
Recall	Medline Industries Inc	Convenience kits
Recall	Medline Industries Inc	Convenience Kits
Recall	MAQUET Cardiopulmonary GmbH	Custom Tubing Packs (CTPs)
Recall	Medela INC....	ENFit ExSet Strl 60 2.0ml PV 1ct EN
Recall	Medtronic Inc.	EOPA 3D Arterial Cannulae and EOPA Elongated One-Piece Arterial Cannulae
Recall	ABIOMED Inc	Impella Set with smart assist Introducer Kit for Impella CP

Medline Convenience kits containing recalled Swan-Ganz Catheters.	Medline Industries Inc	Recall
Med-Stop Vacuum Controller	Medline Industries Inc	Safety Notification
NephroMax High Pressure Nephrostomy Balloon Catheters	Boston Scientific Corp..	Product Correction
OPN NC	SIS Medical AG...	Recall
Pilling Wecksorb Neurosponges	Teleflex Medical..	Recall
Radial Jaw 4 Biopsy Forceps	Boston Scientific Corp..	Recall
TS Barefiber 6600um, 3m,singleuse, sterile	KLS Martin GmbH + Co. KG	Recall
Various procedure packs containing BD Connecta Stopcocks	Medline Industries Inc	Product Alert

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

1. The manufacturing companies must 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.
    - 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

Recall	Medline Industries Inc	Medline Convenience kits containing recalled Swan-Ganz Catheters.
Safety Notification	Medline Industries Inc	Med-Stop Vacuum Controller
Product Correction	Boston Scientific Corp..	NephroMax High Pressure Nephrostomy Balloon Catheters
Recall	SIS Medical AG...	OPN NC
Recall	Teleflex Medical..	Pilling Wecksorb Neurosponges
Recall	Boston Scientific Corp..	Radial Jaw 4 Biopsy Forceps
Recall	KLS Martin GmbH + Co. KG	TS Barefiber 6600um, 3m,singleuse, sterile
Product Alert	Medline Industries Inc	Various procedure packs containing BD Connecta Stopcocks

بناءً على ذلك، فإنّ 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.
    - 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 للإجراءات التنظيمية وغير مخصص كمحتوى للنشر الإعلامي".

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.

د. نورة خميس الغيثي

وكيل دائرة الصحة

Field Safety Corrective Actions:

Medical device	Manufacturer	Classification	Link
Active Implantable Devices			
Intera Oncology INTERA 3000 Hepatic Artery Infusion Pump, AP-0300H	Boston Scientific Corp..	Recall	Class 2 Device Recall Intera Oncology
Anaesthetic and respiratory devices			
Astral 100/150	ResMed Limited.	Product Correction	SA-28-06-26-1447.pdf
Hillrom VOLARA System	Hill Rom Inc	Recall	Class 1 Device Recall Hillrom Volara
LEONI plus / LEONI plus HFO / LEONI plus transport ventilators	Lowenstein Medical GmbH &Co.KG	Product Correction	SA-30-06-26-1449.pdf
Assistive products for persons with disability			
E-motion M25 Wheels	Alber GmbH	Product Correction	26760-26_kundeninfo_en.pdf
Winn'Motion 150 & 175 patient lift.	WINNCARE Spain	Product Correction	26954-26_kundeninfo_en.pdf
Cardiovascular Devices			
NephroMax™ High Pressure Nephrostomy Balloon Catheters (multiple variants)	Boston Scientific International S.A., Voisins le Bretonneux, France	Product Correction	97598346- Customer FSN & Form English HPRA Ok.pdf
Diagnostic and therapeutic radiation devices			
CyberKnife® System with XChange Robotic Collimator Changer	Accuray Incorporated	Product Correction	UCC-26-06029 Foley Trays MENA FSN letter- Advisory (1).pdf
MR systems with SW versions R11.1 and R12.1	Philips Healthcare	Product Correction	19824-25_kundeninfo_en.pdf
Philips Allura R8.2 systems	Philips Medical Systems Nederland B.V.	Product Correction	SA-30-06-26-1450.pdf
Philips Azurion and Allura Systems	Philips Medical Systems Nederland B.V.	Product Correction	SA-30-06-26-1451.pdf
Electro mechanical medical devices			
Omnipod DASH® Insulin Management System	Insulet Corporation.	Recall	Class 1 Device Recall Omnipod 5 Pods
Philips Avalon Fetal Monitor	Philips Healthcare	Product Correction	Database of Recalls, Product Alerts and Product Corrections - details
ROSA ONE Brain Application	Zimmer Biomet	Product Correction	https://apps.tga.gov.au/Prod/DRAC/arn-detail.aspx?k=RC-2026-RN-00488-1
Hospital hardware			

Field Safety Corrective Actions:

HKH 8820 Wall Holder	MAQUET Cardiopulmonary GmbH	Product Correction	28704-26_kundeninfo_en.pdf
In vitro diagnostic devices			
GC Agar Base (150mm) 10/PK R04030, GC Agar Base (100mm) 10/PK R01460	Remel Inc.	Recall	Class 2 Device Recall Remel GC Agar Base
GLP systems Track Centrifuge Module (CM)	Abbott Automation Solutions GmbH, Hamburg, Germany (Core Diagnostics)	Product Correction	FA26JUN2026-REC_LTR.pdf
Oncomine DX Express Test Panel	Thermo Fisher Scientific Oy	Product Correction	22620-26_kundeninfo_en.pdf
The RIDAPlex Respiratory Pathogens C 16 well Step 1	AusDiagnostics Pty Ltd	Recall	Database of Recalls, Product Alerts and Product Corrections - details
Medical software			
Atrio v5.0.1 and Atrio Plus v1.1.0 - 2.0.0	Alerte Digital Health Pte Ltd	Product Correction	Database of Recalls, Product Alerts and Product Corrections - details
RayCare 2024A SP1 RayCare 2024A SP4	RaySearch Laboratories AB (publ)	Recall	Class 2 Device Recall RayCare 2024A SP1
Non-active implantable devices			
Depuy Synthes, ATTUNE Revision Hinge Knee Hinge Insert Components	DePuy International Limited	Recall	Class 2 Device Recall Depuy Synthes, ATTUNE Revision Hinge Knee Hinge Insert Components
Mariner Polyaxial Head components used within the Mariner Pedicle Screw System	SeaSpine Orthopedics Corporation.	Recall	Database of Recalls, Product Alerts and Product Corrections - details
Phantom Hindfoot TCC/TC Ball Tipped Guide Rod 3.0 x 800mm Sterile	Paragon 28, Inc..	Recall	Database of Recalls, Product Alerts and Product Corrections - details
Short Monobloc Stem Broaches.	Medacta International SA,	Recall	Class 2 Device Recall Short Monobloc Stem Broaches
Single-use device			
10ml Syringe LuerLok Tip	Mentor Texas LP	Recall	Class 2 Device Recall BD 10ml Syringe LuerLok Tip
A M S, ALIGNED MEDICAL SOLUTIONS surgical convenience kit	Windstone Medical Packaging, Inc..	Recall	Class 1 Device Recall A M S, ALIGNED MEDICAL SOLUTIONS surgical convenience kit

Field Safety Corrective Actions:

BLEPHADEMODEX	Laboratories THEA S.A.S	Product Correction	28567-26_kundeninfo_en.pdf
Climber Guiding Catheter 6F 3.5EBU shape	PendraCare International B.V…	Recall	29043-26_kundeninfo_en.pdf
ConvaVAC™ NPWT Dressings	ConvaTec.	Product Correction	29211-26_kundeninfo_en.pdf
Convenience kits	Medline Industries Inc	Recall	Class 2 Device Recall Medline
Convenience Kits	Medline Industries Inc	Recall	Class 2 Device Recall Medline Convenience Kits
Custom Tubing Packs (CTPs)	MAQUET Cardiopulmonary GmbH	Recall	28210-26_kundeninfo_en.pdf
ENFit ExSet Strl 60 2.0ml PV 1ct EN	Medela INC.…	Recall	Class 2 Device Recall Medela
EOPA 3D Arterial Cannulae and EOPA Elongated One-Piece Arterial Cannulae	Medtronic Inc.	Recall	https://apps.tga.gov.au/PROD/DRAC/arn-detail.aspx?k=RC-2026-RN-00464-1
Impella Set with smart assist Introducer Kit for Impella CP	ABIOMED Inc	Recall	Class 1 Device Recall Abiomed 14 Fr x 25 cm Low Profile Introducer Kit for Impella CP
Medline Convenience kits containing recalled Swan-Ganz Catheters.	Medline Industries Inc	Recall	Class 2 Device Recall Medline
Med-Stop Vacuum Controller	Medline Industries Inc	Safety Notification	28568-26_kundeninfo_en.pdf
NephroMax High Pressure Nephrostomy Balloon Catheters	Boston Scientific Corp..	Product Correction	Database of Recalls, Product Alerts and Product Corrections - details
OPN NC	SIS Medical AG…	Recall	26114-26_kundeninfo_en.pdf
Pilling Wecksorb Neurosponges	Teleflex Medical..	Recall	Class 2 Device Recall Pilling Wecksorb Neurosponges
Radial Jaw 4 Biopsy Forceps	Boston Scientific Corp..	Recall	28724-26_kundeninfo_en.pdf
TS Barefiber 6600um, 3m,singleuse, sterile	KLS Martin GmbH + Co. KG	Recall	28126-26_kundeninfo_en.pdf
Various procedure packs containing BD Connecta Stopcocks	Medline Industries Inc	Product Alert	Database of Recalls, Product Alerts and Product Corrections - details