

Date: May 10th, 2021

Control Number: 5920

URGENT FIELD SAFETY NOTICE

Dear Valued Customer,

Henry Schein has become aware of a quality issue from our Private-Label manufacturing partner, Delta Med S.p.A., related to their professional contract sterilization service provider, Steril Milano S.r.l. Steril Milano S.r.l. conducted an internal investigation which revealed that the sterility of certain products they processed may have been compromised. As a result, Henry Schein has placed a hold on the impacted specific products lots listed on **Page 2-3** and is working with the appropriate regulatory authorities to address this issue. We request you take the immediate actions listed below.

Clinical impact:

The usage of non-sterile medical devices in a clinical environment may lead to an increased risk of infection which may cause severe damages. Delta Med S.p.A. has not identified any notice of adverse event or serious damage to patients which might be linked to this field safety corrective action. If the product has already been used, no patient follow-up activity is needed.

Actions Required:

1. **CHECK** all locations to confirm if you have any units of the affected products/lot numbers in your possession by utilizing **Table A– Affected Product** on **Page 2 - 3** of this notification.
2. **SEGREGATE and QUARANTINE** all products/lots listed in **Table A– Affected Product** on **Page 2 -3** of this notification.
3. **NOTIFY** any one whom you may have distributed or forwarded product affected by this notification.
4. **RETURN** Only the specified items/lot numbers listed on **Page 2 - 3** purchased from Henry Schein Services GmbH.

Return Address

Henry Schein Services GmbH
Am Heisterbusch 9
D-19258 Gallin
Germany / Deutschland

Please enclose this letter with the return goods.

5. **COMPLETE** the enclosed acknowledgment form and return either by email karen.liu@henryschein.de. Please respond even if you are not affected by this notification.

If you have further questions, please contact karen.liu@henryschein.de. We recognize the criticality of this issue and we appreciate your understanding and patience.

Sincerely,

TABLE A – Affected Product	
HSI Product Code	Product Description
9009426	Winged needle infusion set - gray - 27G - 0,4mm - 20mm
9009427	Winged needle infusion set - orange - 25G - 0,5mm -20mm
9009428	Winged needle infusion set - blue - 23G - 0,6mm -20mm
9009429	Winged needle infusion set - black - 22G - 0,7mm - 20mm
9009430	Winged needle infusion set - green -21G - 0,8mm - 20mm
9009431	Winged needle infusion set - beige - 19G - 1,1mm -20mm
9009432	Winged needle infusion set - rose - 18G - 1,2mm - 20mm
9009433	I.V. catheter with port and wings - G14 - orange - 2,0mm - 45mm
9009434	I.V. catheter with port and wings - G16 - gray - 1,75mm - 45mm
9009435	I.V. catheter with port and wings - G17 - 45mm - Ø1,5mm - white
9009436	I.V. catheter with port and wings - G18 - 45mm - Ø1,3mm - green
9009437	I.V. catheter with port and wings - G20 - 32mm - Ø1,0mm - rose
9009438	I.V. catheter with port and wings - G22 - 25mm - Ø0,9mm - blue
9009439	I.V. catheter with port and wings - G24 - 19 mm - Ø0,74mm - yellow
9009915	I.V. catheter with port and wings - G26 - violet - 0.64mm - 19mm
9009440	I.V catheter straight No Port without wings- G14 - 45mm - orange
9009441	I.V catheter straight No Port without wings - G16 - 45mm - gray
9009442	I.V catheter straight No Port without wings - G18 - 32mm - green
9009443	I.V catheter straight No Port without wings - G18 - 45mm - green
9009444	I.V catheter straight No Port without wings - G20 - 32 mm - rose
9009445	I.V catheter straight No Port without wings - G22 - 25mm - blue
9009446	I.V catheter straight No Port without wings - G24 - 19mm - yellow
9009447	I.V catheter straight No Port with wings - G14 - 45 mm -orange
9009448	I.V catheter straight No Port with wings - G16 - 45 mm - gray
9009449	I.V catheter straight No Port with wings - G18 - 32mm - green
9009450	I.V catheter straight No Port with wings - G18 - 45mm - green
9009451	I.V catheter straight No Port with wings - G20 - 32 mm - rose
9009452	I.V catheter straight No Port with wings - G22 - 25 mm - blue
9009453	I.V catheter straight No Port with wings - G24 - 19 mm - yellow
9009454	IV Catheter VET G14 x70mm
9009455	Obturator G24 for dual entry catheter
9009456	Obturator G22 for dual entry catheter
9009457	Obturator G20 for dual entry catheter

9009458	Obturator G18x45mm for dual entry catheter
9009459	Obturator G17 for dual entry catheter
9009460	Obturator G16 for dual entry catheter
9009461	Obturator G14 for dual entry catheter
9009462	Obturator G24 for single entry catheter
9009463	Obturator G22 for single entry catheter
9009464	Obturator G20 for single entry catheter
9009468	Obturator G18x45mm for single entry catheter
9009465	Obturator G18x32mm for single entry catheter
9009466	Obturator G16 for single entry catheter
9009467	Obturator G14 for single entry catheter

URGENT FIELD SAFETY NOTICE Henry Schein Response Form

	Please read each question below and check the answer you have chosen	Yes	No
1.	Did you read and understand the information that has been provided and will follow the necessary instructions to ensure the proper actions will be taken?		
2.	Did you receive shipments of the impacted product? <i>(If no, please sign and return the form)</i>		
3.	Do you currently have any of the impacted product on hand?		
4.	If yes to question 3, the total number of products quarantined?		
5.	Did you further distribute or forward the impacted product?		
6.	If yes to question 5, the total number of impacted customers?		
7.	Did you notify the impacted customers of this URGENT Field Safety Notice <i>(If yes, please provide a copy of the notification)</i>		
8.	Did you notify your Authorized Representative? <i>If no, please explain why below.</i>	Date Notified:	

FORWARD RESPONSES ONLY TO:
Email: karen.liu@henryschein.de

Person/function responsible for the receipt and management of URGENT Field Safety Notices at your facility

Company Name and Country:	
Print Name and Title:	
Signature:	
Date:	

