المملكة العربية السعودية
الهيئة العامة للغذاء والدواء
Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Medical Device Sector
Surveillance & Biometrics Executive Department

قطاع الأجهزة والمنتجات الطبية
الإدارة التنفيذية للرقابة والقياسات الحيوية

Safety Communication رسالة سلامة

Sterility not guaranteed

Device/ Product Description:	Disposable cuffs for tourniquet application	
Affected products:	**Article number**	**Description**
	UT 1332-XL	Disposable cuff XL, orange connector 860 x 100 mm (34 x 4 in)
	UT 1331-S	Disposable cuff S, green connector 495 x 100 mm (18 x 4 in)
	UT 1332-S	Disposable cuff S, orange connector 495 x 100 mm (18 x 4 in)
	UT 1330-L	Disposable cuff L, standard connector 760 x 100 mm (30 x 4 in)
	UT 1330-M	Disposable cuff M, standard connector 600 x 100 mm (24 x 4 in)
	UT 1332-2XL	Disposable cuff 2XL, orange connector 1070 x 100 mm (42 x 4 in)
	UT 1330-XL	Disposable cuff XL, standard connector 860 x 100 mm (34 x 4 in)
	UT 1331-M	Disposable cuff M, green connector 600 x 100 mm (24 x 4 in)
	UT 1330-S	Disposable cuff S, standard connector 495 x 100 mm (18 x 4 in)
	UT 1332-XL-P	Disposable cuff XL parallel, orange connector Konnektor, 860 x 100 mm (34 x 4 in)
	UT 1332-XS	Disposable cuff XS, orange connector 300 x 90 mm (12 x 4 in)
	UT 1332-M	Disposable cuff M, orange connector, 600 x 100 mm (24 x 4 in)
	UT 1330-2XL	Disposable cuff 2XL, orange connector 1070 x 100 mm (42 x 4 in)
	UT 1330-XL-P	Disposable cuff XL- parallel, standard connector ,860 x 100 mm (34 x 4 in)
	UT 1332-L	Disposable cuff L, orange connector, 760 x 100 mm (30 x 4 in)
	UT 1330-XS	Disposable cuff XS, standard connector 300 x 90 mm (12 x 4 in)
	UT 1332-2XS	Disposable cuff 2XS, orange connector, 200 x 70 mm (8 x 3 in)
	UT 1330-2XS	Disposable cuff 2XS, standard connector 200 x 70 mm (8 x 3 in)
	UT 1332-2XS	Disposable cuff 2XS, orange connector, 200 x 70 mm (8 x 3 in)
	UT 1330-2XS	Disposable cuff 2XS, standard connector 200 x 70 mm (8 x 3 in)
Manufacturer:	Ulrich GmbH & Co. KG	
Problem:	Sterilization parameters deviating from the specifications were identified. The inadequate sterility of the products may result in contamination of the operating room personnel in the sterile field during handling.	

<table>
<tr><td>Recommendation/Actions:</td><td colspan="2">

Make sure that this document is reached to the end-users.
Identify the and dispose affected product.
Contact the authorized representative for the 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
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<tr><td rowspan="4">Authorized Representative Details</td><td>AR name:</td><td>Isam Economic Company Limited</td></tr>
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