



Urgent Field Safety Notice

Product: Warming Solution Set 205
Warming Kit 102
Vitrification Solution Set 110
Vitrification Kit 101

FSCA identifier : 20190521

Type of action : The return of a medical device to the supplier

Date: May 23, 2019

Attention:

Details on affected devices:

Warming Solution Set 205 (Solutions)
Warming Kit 102 (Solutions + Plate)
Vitrification Solution Set 110 (Solutions)
Vitrification Kit 101 (Solutions + Plate + Cryotec)
Value Pack LL (VK101x47, WK102x47)
Value Pack SS (VK101x4, WK102x4)

For affected lots see Annex

Description of the problem:

Unapproved Class III device called Solution was placed in a kit containing a Class IIa devices and sold in the EU market.

The product named Solution is used for vitrification and is a Class III medical device. Solution has not been reviewed or approved by Notified Body; however, it was sold in the EU market as a kit with approved Class IIa devices. Below are potential risks of the unapproved product use to the patient and user.

- mistreatment
- delayed diagnosis
- delayed treatment
- inappropriate treatment and/or
- transfusion of inappropriate materials

Advise on action to be taken by the user:

- identifying and quarantining the device
- disposal of device
- send the device back to REPROLIFE

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

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The undersign confirms that this notice has been notified the appropriate Regulatory Agency.

REPROLIFE is committed to patient safety and will prevent recurrence of this type of problem.

Signature



Affected Products

Product Name	Lot#	Product Name	Lot#
"Value Pack LL" Vitrification Kit 101 x47 Warming Kit 102 x47	JCHA0217BF	Vitrification Kit 101	JCHA0217YE
	JCHA0217BM		JCHA0217YL
	JCHA0217GE		JCHA0217YM
	JCHA0217GM		JCHA0218BG
	JCHA0217RE		JCHA0218GE
	JCHA0217RO		JCHA0218WF
	JCHA0217WE		JCHA0218YH
	JCHA0217WKF		JCHA0219BA
	JCHA0217WL		JCHA0219BB
	JCHA0217YE		JCHA0219GA
JCHA0217YL	JCHA0219GB		
"Value Pack SS" Vitrification Kit 101 x4 Warming Kit 102 x4	JCHA0216GC		JCHA0219RC
	JCHA0216RC		JCHA0219WA
	JCHA0216WB		JCHA0219WSP
	JCHA0216YB		JCHA0219YA
Vitrification Kit 101	JCHA0213BD		JCHA0220BE
	JCHA0215BE		JCHA0220GF
	JCHA0215BH		JCHA0220RF
	JCHA0215BJ		JCHA0220WE
	JCHA0215BK		JCHA0221BD
	JCHA0215GI		JCHA0222BF
	JCHA0215GK		JCHA0222BG
	JCHA0215GL		JCHA0222GH
	JCHA0215RJ		JCHA0222GI
	JCHA0215RL		JCHA0222RF
	JCHA0215RM		JCHA0222RG
	JCHA0215WI		JCHA0222RH
	JCHA0215WL		JCHA0222RI
	JCHA0215YH		JCHA0222WH
	JCHA0215YK		JCHA0222WI
	JCHA0216BB	JCHA0222YG	
	JCHA0216GB	JCHA0222YH	
	JCHA0216GC	JCHA0214VSD	
	JCHA0216RC	JCHA0214VSH	
	JCHA0216WB	JCHA0215VSB	
	JCHA0216YB	JCHA0215VSC	
	JCHA0217BF	JCHA0215VSG	
	JCHA0217BM	JCHA0216VSA	
	JCHA0217BN	JCHA0216VSD	
	JCHA0217GE	JCHA0216VSM	
	JCHA0217GM	JCHA0216VSN	
	JCHA0217GN	JCHA0217VSC	
	JCHA0217RE	JCHA0217VSE	
	JCHA0217RO	JCHA0217VSk	
	JCHA0217RP	JCHA0217VSN	
JCHA0217WE	JCHA0217VSO		
JCHA0217WL	JCHA0218VSF		
		Vitrification Solution Set 110	

Affected Products

Product Name	Lot#	Product Name	Lot#
Vitrification Solution Set 110	JCHA0219VSA	Warming Solution Set 205	JCHA0217WSa
	JCHA0219VSG		JCHA0217WSf
	JCHA0219VSH		JCHA0217WSg
	JCHA0220VSB		JCHA0217WSI
	JCHA0220VSC		JCHA0217WS
	JCHA0220VSD		JCHA0217WSX
	JCHA0220VSE		JCHA0218WSa
	JCHA0220VSI		JCHA0218WSB
	JCHA0220VSJ		JCHA0218WSE
	JCHA0220WKC		JCHA0218WSH
	JCHA0222VSH		JCHA0218WSL
	JCHA0223VSA		JCHA0218WSS
	JCHA0223VSD		JCHA0218WSZ
	JCHA0223VSE		JCHA0219VSA
	JCHA0224VSC		JCHA0219VSB
	JCHA0225VSJ		JCHA0219WS
	JCHA0226VSA		JCHA0219WSI
	JCHA0226VSB		JCHA0219WSJ
	JCHA0226VSC		JCHA0219WSK
	Warming Kit 102		JCHA0214WKF
JCHA0216WKF		JCHA0219WS	
JCHA0216WK		JCHA0219WSV	
JCHA0217WKF		JCHA0220WSH	
JCHA0218WKA		JCHA0220WSI	
JCHA0220WKC		JCHA0220WSL	
JCHA0220WKL		JCHA0220WS	
JCHA0220WKP		JCHA0220WS	
JCHA0222WKK		JCHA0221WS	
JCHA0222WK		JCHA0222WSA	
JCHA0222WKN		JCHA0222WSX	
JCHA0222WKO		JCHA0222WSZ	
JCHA0222WKP		JCHA0223WSE	
JCHA0224WKL		JCHA0224WS	
JCHA0226WKA		JCHA0224WSS	
Warming Solution Set 205	JCHA0213WSc	JCHA0225WS	
	JCHA0213Wsd	JCHA0225WSA	
	JCHA0214WSK	JCHA0225WSF	
	JCHA0215WS	JCHA0225WSV	
	JCHA0215Wsg	JCHA0226WSB	
	JCHA0215WSL		
	JCHA0215WSV		
	JCHA0215WSX		
	JCHA0216WSH		
	JCHA0216WSL		
	JCHA0216WSM		
	JCHA0216WSQ		
JCHA0216WSS			