



FSN Reference: FSCA012019
FSCA Reference: 2019052459
Type of action: FSN

Urgent Field Safety Notice

Date: 15. November 2019
Attention: Danish Regional Hospitals, Distributors, SSI

Follow up from the communication made in February 2019

Contact details of your local KiiltoClean A/S representative:

Ninette Jensen, Salgs- og Markedschef
KiiltoClean A/S | Frederik Plums Vej 2, DK-5610 Assens
Telefon 6471 2112, E-mail info@plum.dk

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

This means, if you are a distributor, this information must be forwarded to any customers that has received the affected devices.

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



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Details on affected devices:

Device Commercial name	WipeClean Chlorine Disinfection Wipes (Large)	WipeClean Chlorine Disinfection Wipes (Small)
Description	Single use wipes, intended for disinfecting surfaces of non-invasive medical devices within healthcare and care environments.	
Purpose of product	To help provide high level disinfection.	
Picture		
Article code	5242	5241
Packaging	24 x 5 wipes	20 x 10 wipes
Affected batch numbers	Products manufactured before February 2019.	
How to find the batch number		



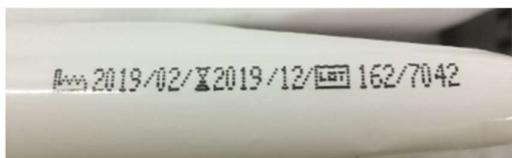
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Description of the problem:

Description of the problem with the devices	On completion of the first real time stability study it was suggested that the shelf life of the product was 10 months rather than 18 months.
Hazard giving rise to the FSCA	The device may not deliver 1000ppm of free chlorine during disinfection.
Probability of problem arising	It is highly unlikely that a product manufactured before February 2019 would provide 1000ppm of free available chlorine after a 10 month shelf life.
Background on issue	The products manufactured before February 2019 were labelled with a 18 month shelf life. Once our first real time stability completed it was suggested that the amount of free available chlorine was below 1000ppm between 10 and 12 months.
Other information relevant to the FSCA	The various stability studies also confirmed that storage at high temperatures >30°C would have a further negative impact on the shelf life of the product. This was highlighted on the product label. 

Advise on action to be taken by the user to mitigate the risk:

Action to be taken by the user	Quarantine any products manufactured before February 2019 and contact KiiltoClean A/S.
By when	5 th December 2019.
Is a reply required	Yes. Please contact KiiltoClean A/S, Susanne Pedersen by phone 6371 0922 or E-mail susanne.pedersen@kiilto.com for further instruction.
Action taken by manufacturer	All products manufactured since Feb 2019 carries a 10 month shelf life: 



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Transmission of this Field Safety Notice:

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Please return this acknowledgement

Please acknowledge receipt of this communication by completing and returning the attached reply form by 5th December 2019. Please return it by E-mail to susanne.pedersen@kiilto.com.

Please accept our apologies for the inconvenience this issue may have caused.

Yours faithfully

KiiltoClean A/S

Bo Eriksen
Managing Director

Pal International Limited

Perminder Rupra
Managing Director



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Customer Reply Form

1. I confirm receipt of the Field Safety Notice (FSN) and that I read and understood its content.
2. I performed all actions requested by the FSN.
3. The information and required actions have been brought to the attention of all relevant users and executed, including end customers in case of distribution of those products

Company Name	
Address	
Department	
Contact Name	
Title/Function	
Telephone number	
Email address	
Print name	
Signature	
Date	

Please return this acknowledgement to:

KiiltoClean A/S | Frederik Plums Vej 2, DK-5610 Assens
Susanne Pedersen, E-mail susanne.pedersen@kiilto.com