WORLD'S LARGEST CONDOM MAKER

karex

Date: 13th October 2025
Reference Number: FSN – KISB 02/2025

Urgent Field Safety Notice
Pasante Unlubricated Non-Latex Probe Cover (KX07) 72pcs Bulk Pack (UK)

For Attention of ***: Pasante Healthcare Ltd.**

Contact details of local representative (name, e-mail, telephone, address etc)*

Simon Boyd-Jones
Unit 21 Commerce Way, Lancing Business Park Lancing West Sussex,
BN15 8TA,
United Kingdom
Tel: +44 1903 753 844
Email: simon.jones@pasantehealthcare.com

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Risk Address by FSN

1. Information on Affected Devices*	
1.	1. Device Type(s)*
	Non-sterile Non-latex Protective Transducer Covers
1.	2. Commercial Name(s)
	Pasante Unlubricated Non-Latex Probe Cover (KX07) 72pcs Bulk Pack (UK
1.	3. Unique Device Identifier(s) (UDI – DI)
	9556564-NSPIPC-83
1.	4. Primary Clinical Purpose of Device(s)
	For barrier protection during invasive medical examination and diagnosis using transducer probe.
1.	5. Device Model/ Catalogue/ Part Number(s)*
	KX07-non-latex
1.	6. Software Version
	N/A
1.	7. Affected Serial or Lot Number Range
	Lot Number: 25P048 **Exp Date: 2028/04** **MFG Date: 2025/05**
1.	8. Associated Devices
	N/A

2. Reason for Field Safety Corrective Action (FSCA)*	
2.	1. Description of the Product Problem*
	The expiry date printed on the packaging is 28-04-30 whereas the expiry date encoded in the QR code is 08-04-30, indicating discrepancy between the printed and encoded information.
2.	2. Hazard Giving Rise to the FSCA*
	The incorrect expiry date encoded in the QR code may cause misinterpretation of the product's shelf life.

2.	3. Probability of Problem Arising
	This problem arising is very low, as it affects only the QR code on this specific lot. The printed expiry date on the packaging is correct and the discrepancy is observed only when the QR code is scanned by end users.
2.	4. Predicted Risk to Patient/ Users
	The risk to users is considered negligible. The discrepancy is limited to the expiry date encoded in the QR code, while the printed expiry date on the packaging is correct. This issue does not affect the product's quality, safety or performance and there is no impact on the effectiveness or usability of the product when used as intended.
2.	5. Further Information to Help Characterize the Problem
	N/A
2.	6. Background on Issue
	During routine checks by the customer, it was identified that the expiry date encoded in the QR code on this lot of the product differs from the expiry date printed on the packaging. The printed expiry date is 28-04-30 whereas the QR code shows 08-04-30. **The discrepancy was traced to data encoding error during the QR code generation process. The QA inspection process did not detect the mismatch and the affected lot was released with the incorrect QR code. The issue is limited to the QR code and does not affect the product's quality, safety, or performance.**
2.	7. Other Information Relevant to FSCA
	N/A

3. Type of Action to Mitigate the Risk*		
3.	1. Action to be Taken by User*	
	☐ Identify Device ☐ Quarantine Device ☐ Return Device ☐ Destroy Device ☐ On – site Device Modification/ Inspection ☐ Follow Patient Management Recommendation ☐ Take Note of Amendment/ Reinforcement of Instruction for Use (IFU) ☐ Other ☒ None: Inform all affected customers of the discrepancy between the expiry date printed on the packaging (**28-04-30**) and the expiry date encoded in the QR code (**08-04-30**). Advise them to refer to the **printed expiry date** as correct. This discrepancy does not affect product quality, safety, or performance.	
3.	2. By When Should the Action be Completed?	**13th December 2025**
3.	3. Probability of Problem Arising: **Rare** Is Follow – Up of Patients or Review of Patients' Previous Results Recommended? No follow-up is required as the discrepancy only involves the expiry date in the QR code and does not affect the product's quality, safety, or performance.	
3.	4. Is Customer Reply Required?* **Yes** (if yes, form attached specifying deadline for return)	Concession acknowledgement by **N/A**

3.	5. Further Information to Help Characterise the Problem ☐ Product Removal ☐ On – Site Device Modification/ Inspection ☐ Software Upgrade ☐ IFU or Labelling Change ☐ Other: ☒ None	
3.	6. By When Should the Action Completed?	**N/A**
3.	7. Is the FSN Required to be Communicated to the Patient/ Lay User?	**Not required**
	8. If Yes, has Manufacturer Provided Additional Information Suitable for the Patient/ Lay User in a Patient/ Lay User or Non – Professional User Information Letter/ Sheet?	
	N/A	

4. General Information		
4.	1. FSN Type*	**Advisory Notice**
4.	2. For Updated FSN, Reference Number and Date of Previous FSN	**N/A**
4.	3. For Updated FSN, Key New Information as Follows:	
	N/A	
4.	4. Further Advise or Information Already Expected in Follow – Up FSN?*	**N/A**
4.	5. If Follow – Up FSN Expected, what is the Further Advice Expected to Relate to:	
	N/A	
4.	6. Anticipated timescale for follow – up FSN	**N/A**
4.	7. Manufacturer information (For contact details of local representative refer to page 1 of this FSN) a. Company Name: N/A b. Address: N/A c. Website Address: N/A	
4.	8. The Competent (Regulatory) Authority of your country has been informed about this communication to customer. **Not required as the issue does not affect product quality, safety or performance.**	
4.	9. List of attachments/ appendices:	**N/A**
4.	10. Name/ Signature	**Ivy Ng Wen June/ Group Quality Compliance Assistant Manager** 

Transmission of this Field Safety Notice	
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device – related incidents to the manufacturer, distributor or local representative, and the National Competent Authority if appropriate, as this provides important feedback.*

Note: Fields indicated by * are considered necessary for all FSNs. Others are optional.