R06 FIELD_SAFETY_NOTICE_ 2026-011-012-601-036

Medicare Colgate Ltd
Unit 1/2 Post Cross Business Park, Cullompton, Devon, EX15 2BB
Tel: 01884 266666

URGENT FIELD SAFETY NOTICE

(Field Safety Corrective Action)

FSCA reference number	2026/011/012/601/036
Date of this notice	10/11/26
Product name	Colostrum Collector & Feeder / Colostrum Collector & Feeder with Tethered Cap
Model(s) / catalogue number(s)	11203 (FAX85096) , 11205 (FAX85109), 11205-10 & 11205-25 (FAX85108)
Affected batch / lot / serial numbers	11203 = 240310, 11203 = 240925, 11203 = 250610 & 11203 = 260125 11205= 251110 & 260210 11205- 10 = 251110 11205-25 = 251110
UDI (if applicable)	NA
Type of action	Recall

1. Description of the problem

Due to an administrative error with the product's regulatory certification, the product no longer has CE certification, therefore these products can no longer be sold.

2. Risk to health

No safety risk has been identified, and no adverse incidents have been received.

As this is not a safety issue, we believe that colostrum already stored in syringes is safe to use. We are consulting with MHRA on this issue and will advise further if required.

3. Action to be taken by the recipient

Identify all affected unused units against the lot numbers above;

Please quarantine unused products with immediate effect & please return goods.

Complete and return the FSN acknowledgement form within 7 days of receiving the notice.

4. Patient / user follow-up required

Not Required

5. Transmission of this notice

Please forward this notice to any organisation to which you have supplied this product, and to any relevant department within your own organisation. Please retain a copy of this notice with your quality records for the retention period set out in the FSN acknowledgement form.

If you have further distributed this product, please confirm to us that you have cascaded this notice, using the acknowledgement form below.

6. Regulatory notification

The Medicines and Healthcare products Regulatory Agency (MHRA) has been informed of this Field Safety Corrective Action.

7. Contact for further information

Name: Sally Roberts

Role: Sales Manager

Tel: 01884 266666

Email: sally@Sterifeed.com

Name: Daniel Hall

Role: Quality Manager

Tel: 01884 266666

Email: daniel@sterifeed.com

FSN ACKNOWLEDGEMENT AND RESPONSE FORM

Please complete and return this form to the contact named in Section 7 by [date], even if you hold no affected stock.

FSCA reference number	*[As shown above]*
Your organisation name	
Your account / customer reference	
Completed by (name and role)	
Date completed	
Do you hold, or have you supplied, any affected product? (Y/N)	
If yes, quantity currently held and what product codes.	
If yes, quantity already used/supplied to others before this notice	
Have you completed the action required in Section 3? (Y/N, details)	
Have you cascaded this notice to any organisation you supplied? (Y/N, to whom)	
Any adverse events or health effects to report in connection with this issue?	
Signature	

Please return this form to: daniel@sterifeed.com