

MTN Neubrandenburg GmbH  
Gustav-Kirchhoff Straße 2 – 17033 Neubrandenburg

## TO WHOM IT MAY CONCERN

Neubrandenburg, 07 April 2021

### **Field safety Notice MTN - 01- 2021**

**Citrasate®, Type code 484, Lot Number 29420520 calcium free 5,5 l bags**

**Citrasate®, Type code 489, Lot Number 29410520 calcium free 5,5 l Bags**

Dear Sir or Madam,

We, MTN Neubrandenburg GmbH hereby declare that we like to recall a product that might cause an incident to patients due to an inaccuracy in the labelling.

We delivered our distributor

Hemotech

19 avenue de l'Europe

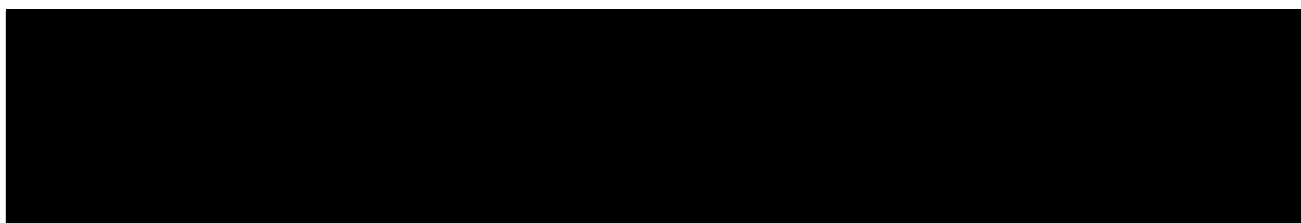
31522 Ramonville Saint-Agne FRANCE

France

With the following products that are involved in this incident:

### **Details of the affected products**

Article code (MTN)	Lot number	Product	Packaging
484	29420520	Citrasate®, calcium free	5,5 liter bag
489	29410520	Citrasate®, calcium free	5,5 liter bag



### **Description of the problem**

The design of product label (colour marking) is incorrect but the composition present on the bag and the cardboard box label is correct and in accordance with the specification.

The unprinted bag label should be coloured with a red frame and a red watermark for calcium free products "Ca 0". The wrong unprinted label shows yellow mark, the same as used in general for Citrasate®. The cardboard box label is the correct version. Please find the detailed information of the labelling attached.

Since the yellow bag label has resulted to an accidental mix-up of Citrasate® products with and without calcium which could lead to an serious hazards for patients, we decided to recall this batches.

### **Advice on action to be taken**

With this information letter we request you to send back to Hemotech immediately all affected products listed above. Together with Hemotech we will coordinate replacement of products.

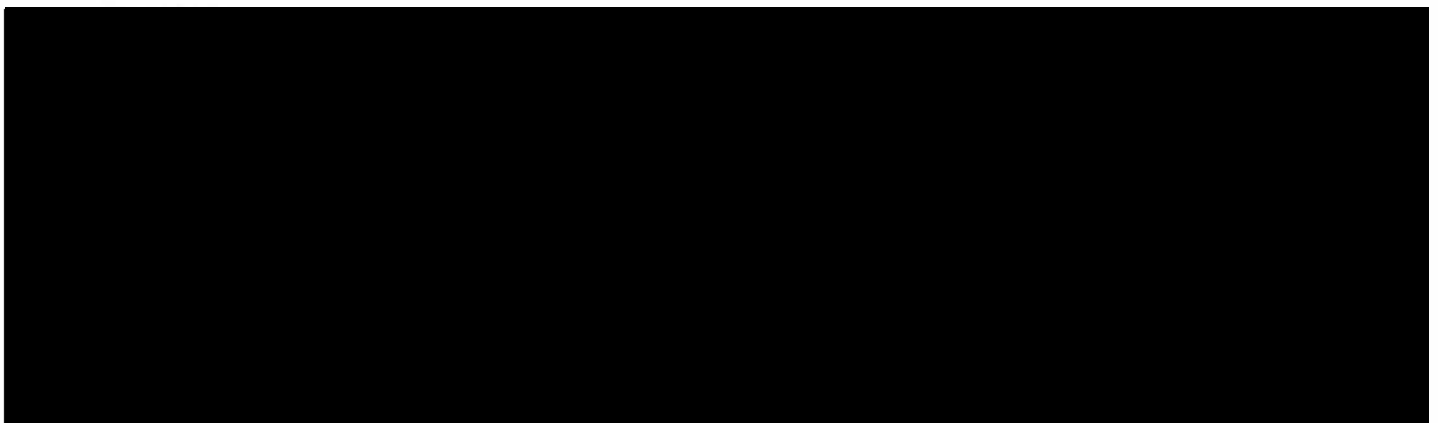
As this incident is related to patient's health, an FSN was issued, and this incident will be reported to the relevant authorities and our Notified Body BSI.

### **Contact reference person**

In case of question please contact **materiovigilance@hemotech.fr**

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

Sincerely yours,



## Annex Customer and reply form

To be read together with the Field Safety Notice FSN Field safety Notice MTN-01-2021

Send back the filled and signed form as quickly as possible to the following address:  
[materiovigilance@hemotech.fr](mailto:materiovigilance@hemotech.fr)

☐ I confirm that the communication has been read, understood and that all recommended actions have been performed as requested

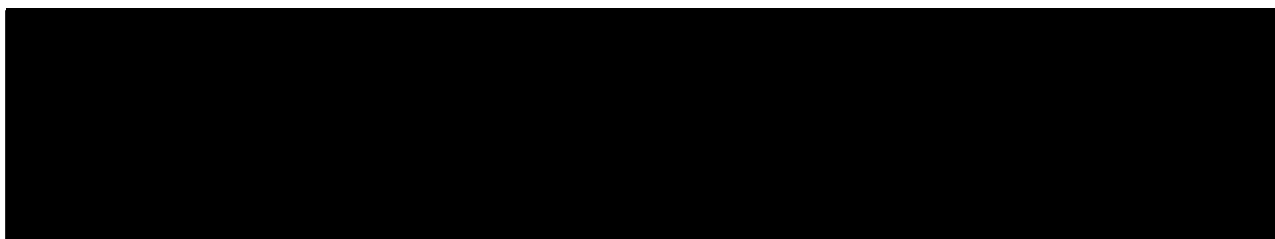
Tick the appropriate box here below

☐ We do not have in our stock the medical device listed below

☐ We have in our possession the medical device listed in the Field Safety Notification and we confirmed that the following quantities have been quarantined as stated below

Reference Code article MTN	Lot number	Quarantined quantity
484	29420520	

Name of the Hospital	
Department (if applicable)	
Address :	
Contact person:	
Role at the internal organisation :	
Email address :	
Telephone number :	
Signature and stamp :	



## Attachment Field safety Notice MTN - 01- 2021

Product labels

Art. Code: 484; Lot 29420520

Cardboard box label -> correct

**ATTENTION !** Calcium frei / Calcium free / SANS CALCIUM

**Citrasate**® Acid Concentrate for Bicarbonate Dialysis **484** 

**K 3,00** Ca **0,00** Gluc **1,00** **2x5,5Le**

1l 484 + 42.225 l H<sub>2</sub>O ISO 23500-3  
+ 1.775 l NaHCO<sub>3</sub> 8,4%

Natrii chloridum	263,00 g/l	Na <sup>+</sup>	139,75 mmol/l
Kalii chloridum	10,07 g/l	K <sup>+</sup>	3,00 mmol/l
Magnesium chloridum x 6H <sub>2</sub> O	4,57 g/l	Mg <sup>2+</sup>	0,50 mmol/l
Calcii chloridum x 2H <sub>2</sub> O	0,00 g/l	Ca	0,00 mmol/l
Acidum citricum	6,92 g/l	Citrate <sup>3-</sup>	0,80 mmol/l
Natrii acetats x 3H <sub>2</sub> O	1,84 g/l	CH <sub>3</sub> COO <sup>-</sup>	0,30 mmol/l
Glycosum anhydricum	45,00 g/l	HCO <sub>3</sub> <sup>-</sup>	37,04 mmol/l
H <sub>2</sub> O	ad 1000 ml	Cl <sup>-</sup>	104,00 mmol/l
Conductivity (ready to use sol.)	13,71 mS/cm	Glucosum	1,00 g/l

de: Saures Konzentrat (A-Konzentrat) für die Bicarbonat-Hämodialyse (Hinweis: eine Übermischung mit Bicarbonat (B-Konzentrat) ist zu vermeiden) en: Acid concentrate (A-concentrate) for bicarbonate haemodialysis (Note: over mixing with bicarbonate concentrate (B concentrate) should be avoided) fr: le concentré de dialyse acide (concentré A) pour l'hémodialyse au bicarbonate (note: il faut éviter de trop mélanger avec le concentré de bicarbonate (concentré B) nl: Zuur dialyseconcentraat (A-concentraat) voor de bicarbonaat-hemodialyse (let op: vermijd een mix met bicarbonaat -concentraat (B-concentraat).

MTN Neubrandenburg GmbH, Gustav Kirchhoff Str. 2  
17033 Neubrandenburg/ Germany

REF 48400055014 LOT 29420520

5°C 30°C 2023/04 CE 2797

(01)04250319804011(15)230413(10)29420520

Bag label -> as was incorrect

**ATTENTION !** Calcium frei / Calcium free / SANS CALCIUM

**Citrasate**® Acid Concentrate for Bicarbonate Dialysis **484** 

**K 3,00** Ca **0,00** Gluc **1,00** **5,5Le**

1l 484 + 42.225 l H<sub>2</sub>O ISO 23500-3  
+ 1.775 l NaHCO<sub>3</sub> 8,4%

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Kalii chloridum	10,07 g/l	K <sup>+</sup>	3,00 mmol/l
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Calcii chloridum x 2H <sub>2</sub> O	0,00 g/l	Ca	0,00 mmol/l
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Bag label -> as should have been correct

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+ 1.775 l NaHCO<sub>3</sub> 8,4%

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Kalii chloridum	10,07 g/l	K <sup>+</sup>	3,00 mmol/l
Magnesium chloridum x 6H <sub>2</sub> O	4,57 g/l	Mg <sup>2+</sup>	0,50 mmol/l
Calcii chloridum x 2H <sub>2</sub> O	0,00 g/l	Ca	0,00 mmol/l
Acidum citricum	6,92 g/l	Citrate <sup>3-</sup>	0,80 mmol/l
Natrii acetats x 3H <sub>2</sub> O	1,84 g/l	CH <sub>3</sub> COO <sup>-</sup>	0,30 mmol/l
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MTN Neubrandenburg GmbH, Gustav Kirchhoff Str. 2  
17033 Neubrandenburg/ Germany

REF 48400055014 LOT XXXXXXXXXX

5°C 30°C 9999/99 CE 2797

(01)04250319804011(15)999999(10)XXXXXXXXXXXXXXXXXXXX



Product labels  
Art. Code: 489; Lot 29410520

Cardboard box label -> correct

**ATTENTION !** Calcium frei  
Calcium free  
SANS CALCIUM

**Citrasate<sup>®</sup>** Acid Concentrate  
for Bicarbonate Dialysis **489** 

**K 2,00** Ca 0,00 Gluc 1,00 **2x5,5Le**

1l 489 + 42.225 l H<sub>2</sub>O ISO 23500-3  
+ 1.775 l NaHCO<sub>3</sub> 8,4%

Natrii chloridum	263,00 g/l	Na <sup>+</sup>	139,75 mmol/l
Kalii chloridum	6,71 g/l	K <sup>+</sup>	2,00 mmol/l
Magnesi chloridum x 6H <sub>2</sub> O	4,57 g/l	Mg <sup>2+</sup>	0,50 mmol/l
Calcii chloridum x 2H <sub>2</sub> O	0,00 g/l	Ca <sup>2+</sup>	0,00 mmol/l
Acidum citricum	6,92 g/l	Citrate <sup>3-</sup>	0,80 mmol/l
Natrii acetats x 3H <sub>2</sub> O	1,84 g/l	CH <sub>3</sub> COO <sup>-</sup>	0,30 mmol/l
Glycosum anhydricum	45,00 g/l	HCO <sub>3</sub> <sup>-</sup>	37,04 mmol/l
H <sub>2</sub> O	ad 1000 ml	Cl <sup>-</sup>	103,00 mmol/l
Conductivity (ready to use sol.)	13,78 mS/cm	Glucosum	1,00 g/l

de: Saures Konzentrat (A-Konzentrat) für die Bicarbonat-Hämodialyse (Hinweis eine Übermischung mit Bicarbonat (B-Konzentrat) ist zu vermeiden) en: Acid concentrate (A-concentrate) for bicarbonat haemodialysis (Note: over mixing with bicarbonate concentrate (B concentrate) should be avoided) fr: le concentré de dialyse acide (concentré A) pour l'hémodialyse au bicarbonate (note : il faut éviter de trop mélanger avec le concentré de bicarbonate (concentré B). nl: Zuur dialyseconcentraat (A-concentraat) voor de bicarbonaat-hemodialyse (let op: vermijd een mix met bicarbonaat -concentraat (B-concentraat).

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REF 48900055014 LOT 29410520

5°C 30°C 2023/04 CE 2797

(01)04250319804028(15)230413(10)29410520

Bag label -> as was incorrect

**ATTENTION !** Calcium frei  
Calcium free  
SANS CALCIUM

supplémentation calcique obligatoire

**Citrasate<sup>®</sup>** Acid Concentrate  
for Bicarbonate Dialysis **489** 

**K 2,00** Ca 0,00 Gluc 1,00 **5,5Le**

1l 489 + 42.225 l H<sub>2</sub>O ISO 23500-3  
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Calcium free  
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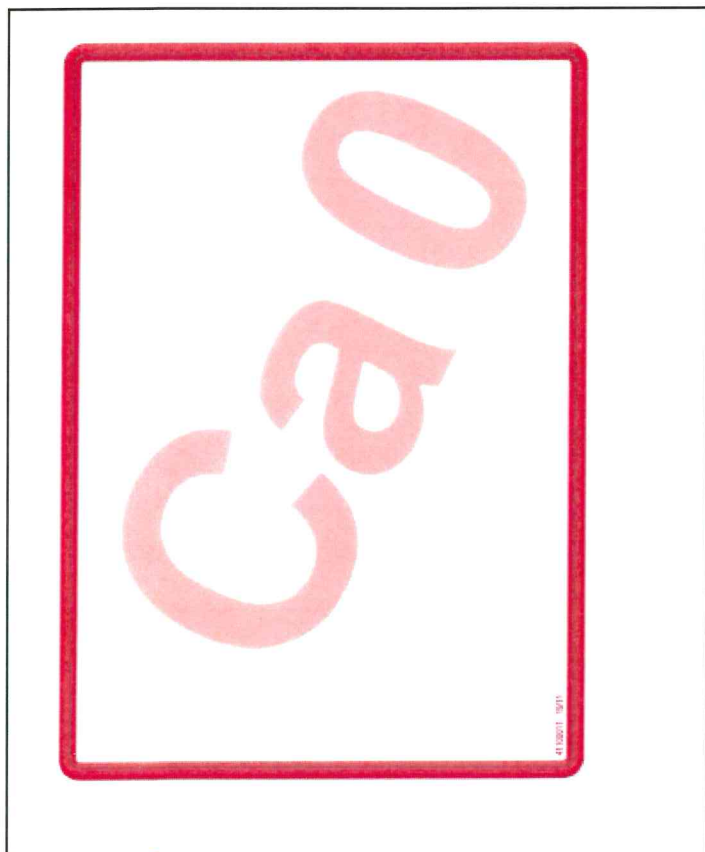
REF 48900055014 LOT XXXXXXXXXXXXX

5°C 30°C 9999/99 CE 2797

(01)04250319804028(15)999999(10)XXXXXXXXXXXXXXXXXXXX

Blank label format

Cardboard box (Label Art.code: 41100011; Ref 19/11)



Bag label (Label Art. Code: 42400003; Ref.20/02)

