URGENT FIELD SAFETY NOTICE
END USERS

Commercial name:

- **Female catheter**
- **Nelaton catheter**
- **Rectal catheter**
- **Mülly suction catheter**

LOT No: Please refer to table on page 13
FSCA Id: 2011/09/CTH3
Type of action: **Recall** – the return of medical devices to the supplier

30th September 2011

Description of the problem:

Unomedical would like to inform you of an irregularity that has occurred with the following medical devices:

- **Female catheter** – this device is intended to intermittently drain urine from the bladder (female). The product is intended for single use only.
- **Nelaton catheter** – this device is intended to intermittently drain urine from the bladder (male). The product is intended for single use only.
- **Rectal catheter** – this device is designed for the administration of medicine, drainage of the rectum or exploration of colostomy. The product is intended for single use only.
- **Mülly suction catheter** – this device is intended for tracheobronchial suctioning of the lower airways to remove excessive excretion. This device is an open system catheter. The product is intended for single use only.

Specific device references and lot information is provided on page 13 of this document.

Selected production lots of the aforementioned medical devices have been found to carry small scratches, or plastic fins, at specific intervals along the body of the device itself.

We have identified the problem as being introduced by an automated packaging machine after the devices had been manufactured. The identified malfunction has now been corrected and the problem rectified.

The defect marks which are present on these catheters pose a risk of inflicting direct trauma (superficial abrasion, irritation) to local tissue relative to their intended use and point of contact.

The use of the affected rectal catheters presents a lesser degree of clinical risk to end-users. However, due to the high frequency of defective rectal catheters we also consider that these devices **should not be used** and should be **recalled**.

To address any potential risk of harm, all of the affected products (which may be identified by the reference and lot numbers using the identification procedure specified on the following pages) are being **recalled**.

Identification Procedure:

The affected devices can be identified by product lot number in conjunction with the product reference number.

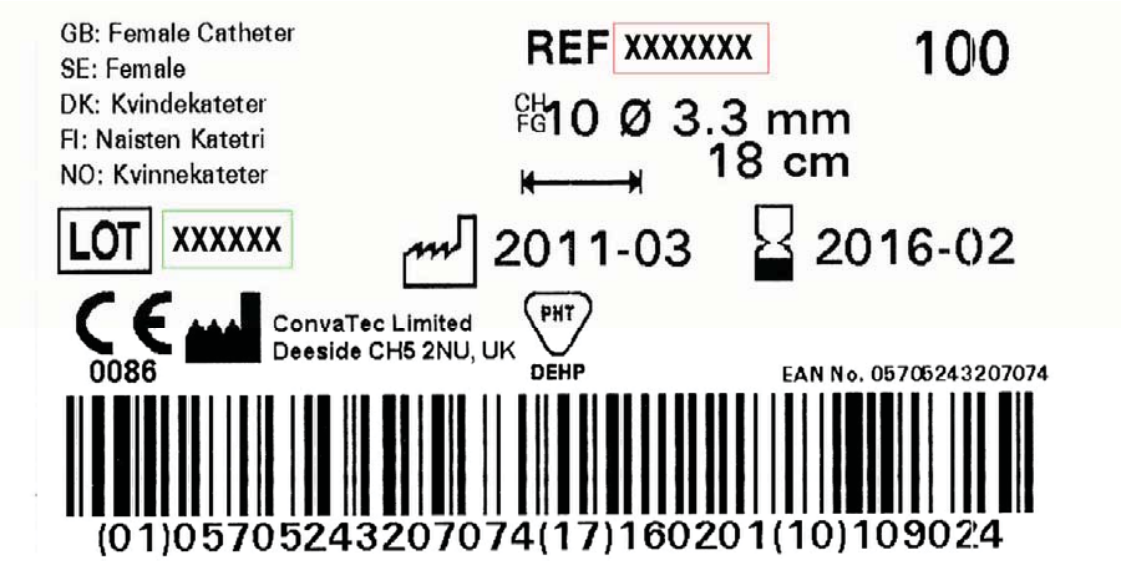
The lot number and reference number can be found on the device label which is located on both the primary packaging as well as the shipping carton.

The reference number, or product code, is demarcated by a green box in **IMAGES 1-4**. The reference number will always be preceded by the word 'REF.'

The lot number is demarcated by a red box in **IMAGES 1-4**. The lot number will always be preceded by the word 'LOT.'

IMAGE 1A
Female Catheter

IMAGE 1B
Female Catheter



Unomedical
A ConvaTec Company

IMAGE 2A
Nelaton Catheter

Unomedical
A ConvaTec Company

IMAGE 2B
Nelaton Catheter

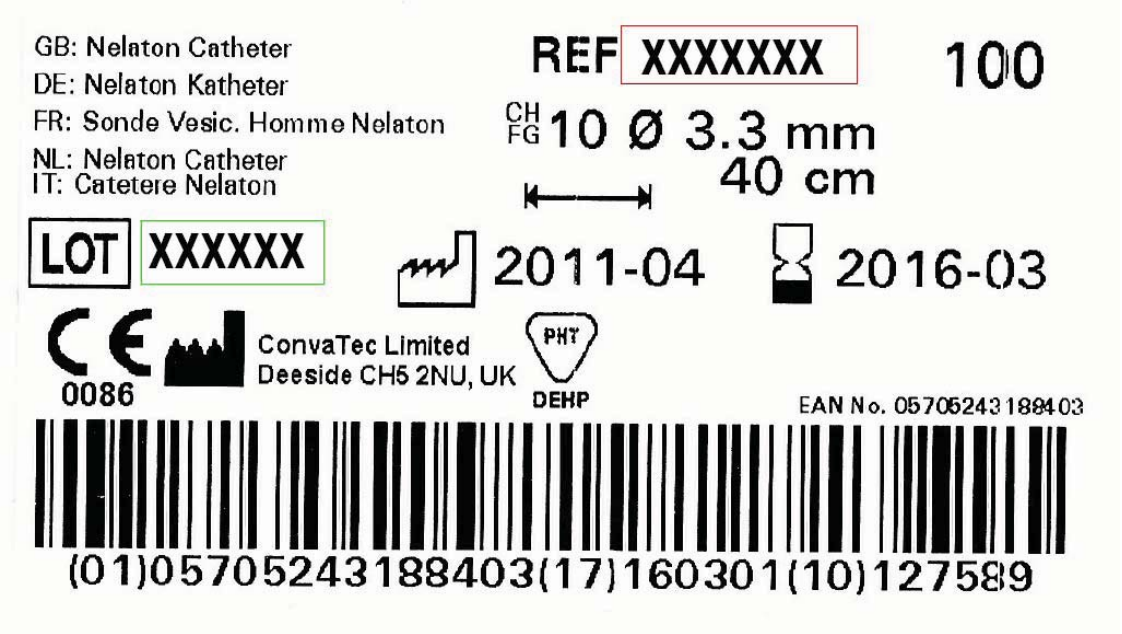
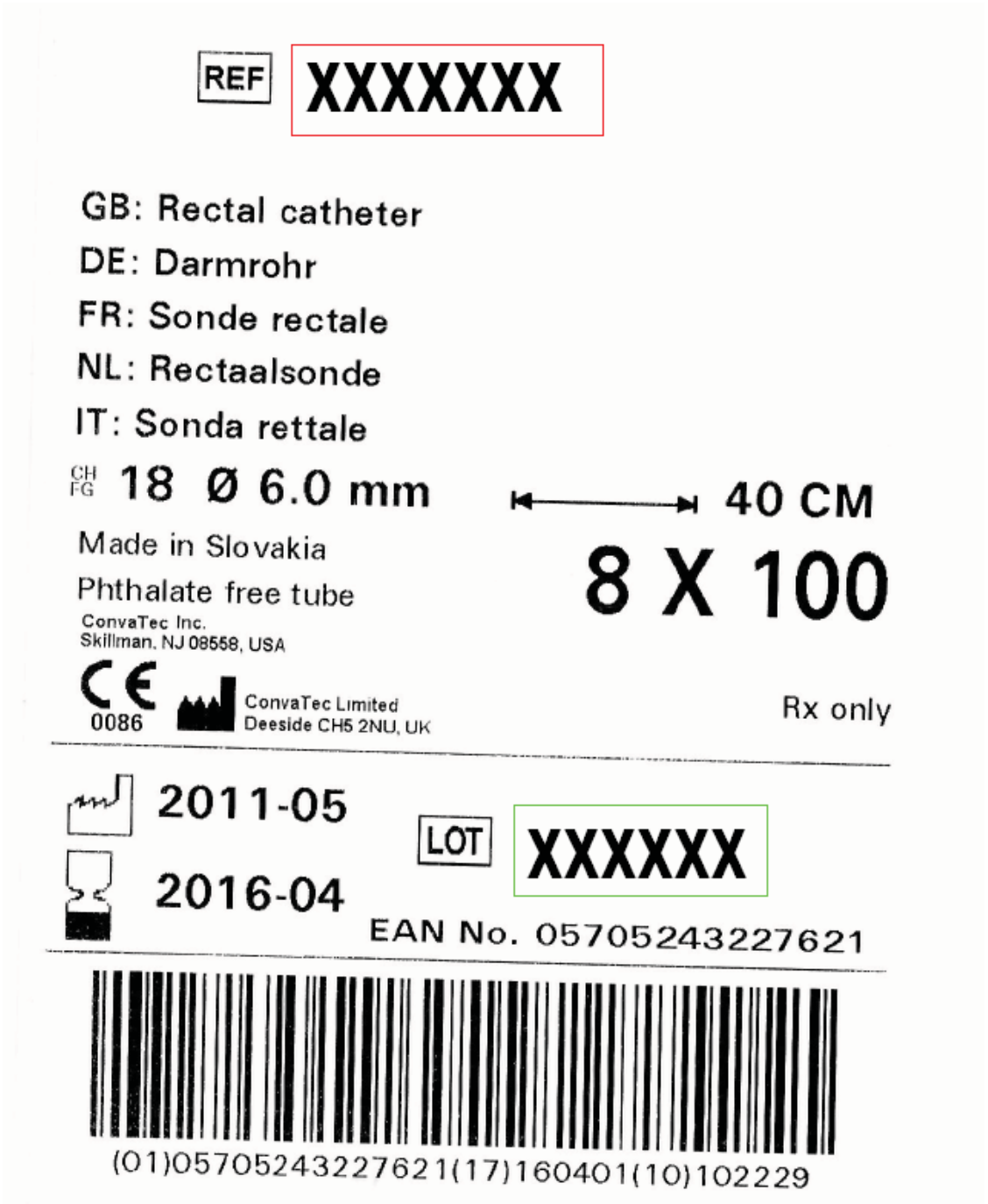
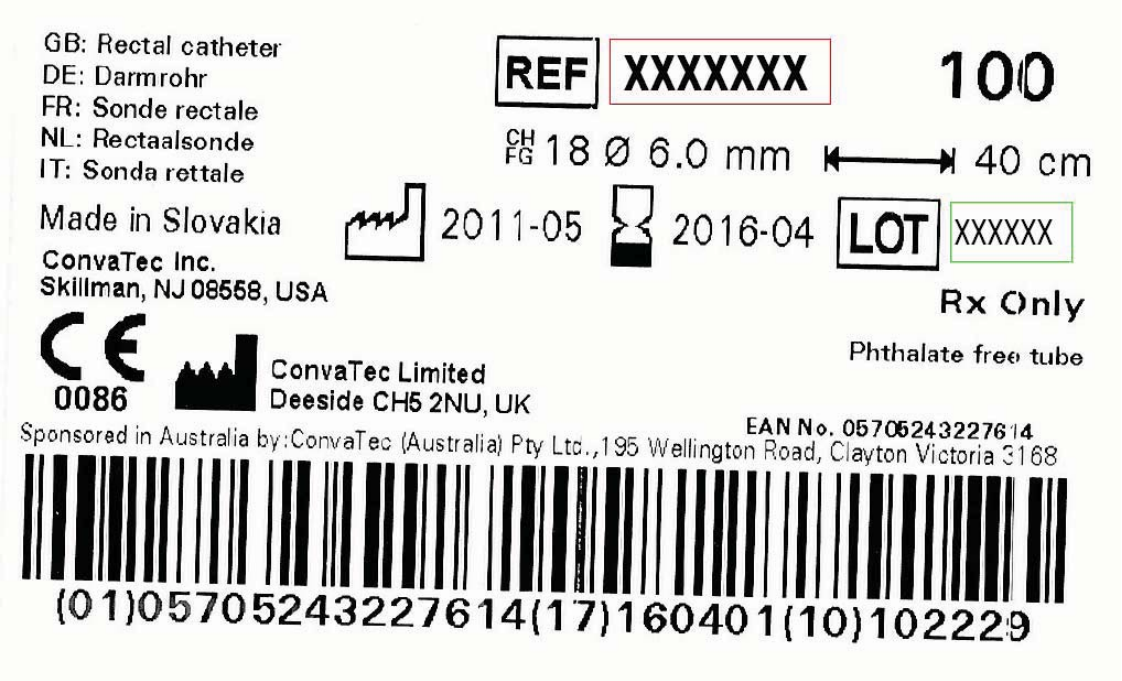


IMAGE 3A
Rectal Catheter



Unomedical
A ConvaTec Company

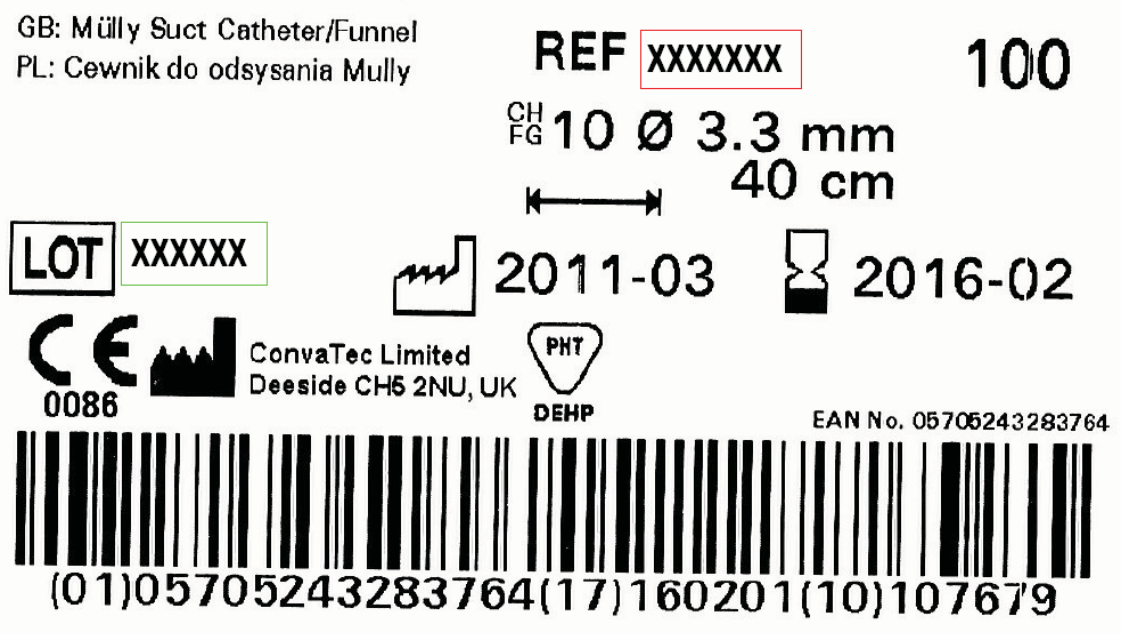
IMAGE 3B
Rectal Catheter



Unomedical
A ConvaTec Company

IMAGE 4A
Mülly suction catheter

IMAGE 4B
Mülly suction catheter



All affected device reference numbers and lot numbers are listed on page 13 of this Field Safety Notice.

Instructions on action to be taken by the user:

Our records show that you have taken delivery of the affected products. Please follow the steps below:

1. Please stop the use of all affected devices as defined in the table on page 13 of this document.
2. Check stock and complete the enclosed questionnaire which should be forwarded to your distributor as soon as possible.
3. Return all affected products to your distributor for credit by 31st October 2011.
4. Please mark all returned product clearly with: “2011/09/CTH3 Recalled Products from *Your Name Here*”

Transmission of this Field Safety Notice:

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.

The relevant National Authorities have been advised about this Field Safety Corrective Action.

Unomedical apologises for any inconvenience this may cause and requests that you share this notice with all relevant customers/users. If you have any questions, please contact your distributor or local Unomedical/ConvaTec representative.

Contact reference person relating to this letter: *(distributor to complete)*

Name:
Position:

Address:

Tel:
Fax:
E-mail:

Unomedical
A ConvaTec Company

AFFECTED DEVICE LISTING

Catheter Description	Product Code (Ref)	Lot Number
Female CH10	02015181	411050
		416231
	02015179	414990
	02015182	412514
		414576
		416067
		417758
	02015183	415776
		418136
	02058022	414600
		417208
		418254
	02058419	417346
		418256
	02058559	417210
	011.10.020	413096
		414999
Female CH12	02016022	411682
		413216
		414578
		416069
	02016179	411564
		415237
	02016181	412324
		414190
		416918
	02016182	412515
		414388
		414582
		416070
		417759
	02016183	411692
		414584
		417198
	02016185	414191
		416920
	02016559	417199

		412517
		414586
		416072
		417200
	02017022	418250
	02017179	414992
		414192
		415484
		416921
	02017181	418185
		412518
		414389
		414589
		414590
		416073
		417761
	02017182	418251
		415778
	02017183	417202
	02017185	416923
	02017419	417345
		417205
	02017559	418769
		413887
Female CH14	011.14.020	415000
		411689
		414594
		416075
	02019022	417206
	02019179	414993
		412315
		415488
	02019181	417370
		411693
		412521
		414390
		416076
	02019182	417763
		415780
		418138
	02019183	419423
Female CH16	02019419	414597
Female CH18	02020181	417371

Nelaton CH10	01007022	417185
	01007183	417186
	01007184	418236
	01007242	418755
	01007559	417188
Nelaton CH12	01008181	417364
	01008182	417365
	01008183	417190
		418133
	01008184	416559
Nelaton CH14	01009022	416061
	01009183	415772
Nelaton CH18	01015419	418242
Rectal CH 18	14003182	414762
Suction Mully CH10	05076181	417378
	05076182	419814
	05076184	419452

RECALL QUESTIONNAIRE FOR END-USERS

Consignee of the device:

NAME:	ADDRESS:	QUANTITY:

The following device(s) have been forwarded to you:

REF:	DEVICE:	LOT No:	QUANTITY:

The recipient confirms (please, tick off as applicable):

_____ that none of the devices mentioned above are in my possession.

_____ that some of the devices mentioned above remain in my possession.
They will be returned as per the instructions given by the distributor.

Number/ Lot(s) to be returned:_____ pieces

_____ _____ _____
NAME (CAPITAL LETTERS) AND POSITION SIGNATURE DATE

_____

ADDRESS

This form has been submitted by a representative of the distributor:

_____ _____ _____
NAME SIGNATURE DATE

URGENT FIELD SAFETY NOTICE
DISTRIBUTOR

Commercial name:

- **Female catheter**
- **Nelaton catheter**
- **Rectal catheter**
- **Mülly suction catheter**

LOT No: Please refer to table on page 13
FSCA Id: 2011/09/CTH3
Type of action: **Recall** – the return of medical devices to the supplier

30th September 2011

Description of the problem:

Unomedical would like to inform you of an irregularity that has occurred with the following medical devices:

- **Female catheter** – this device is intended to intermittently drain urine from the bladder (female). The product is intended for single use only.
- **Nelaton catheter** – this device is intended to intermittently drain urine from the bladder (male). The product is intended for single use only.
- **Rectal catheter** – this device is designed for the administration of medicine, drainage of the rectum or exploration of colostomy. The product is intended for single use only.
- **Mülly suction catheter** – this device is intended for tracheobronchial suctioning of the lower airways to remove excessive excretion. This device is an open system catheter. The product is intended for single use only.

Specific device references and lot information is provided on page 13 of this document.

Selected production lots of the aforementioned medical devices have been found to carry small scratches, or plastic fins, at specific intervals along the body of the device itself.

We have identified the problem as being introduced by an automated packaging machine after the devices had been manufactured. The identified malfunction has now been corrected and the problem rectified.

The defect marks which are present on these catheters pose a risk of inflicting direct trauma (superficial abrasion, irritation) to local tissue relative to their intended use and point of contact.

The use of the affected rectal catheters presents a lesser degree of clinical risk to end-users. However, due to the high frequency of defective rectal catheters we also consider that these devices **should not be used** and be should be **recalled**.

To address any potential risk of harm, all of the affected products (which may be identified by the reference and lot numbers using the identification procedure specified on the following pages) are being **recalled**.

Identification Procedure:

The affected devices can be identified by product lot number in conjunction with the product reference number.

The lot number and reference number can be found on the device label which is located on both the primary packaging as well as the shipping carton.

The reference number, or product code, is demarcated by a green box in **IMAGES 1-4**. The reference number will always be preceded by the word 'REF.'

The lot number is demarcated by a red box in **IMAGES 1-4**. The lot number will always be preceded by the word 'LOT.'

IMAGE 1A
Female Catheter

IMAGE 1B
Female Catheter

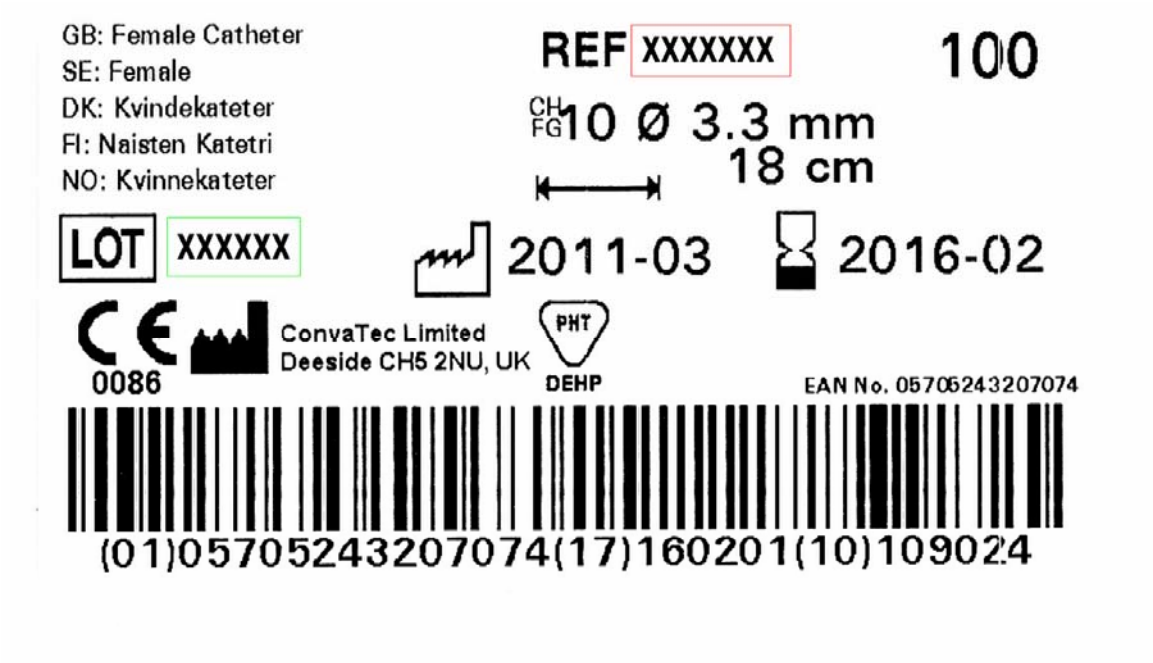


IMAGE 2A
Nelaton Catheter

IMAGE 2B
Nelaton Catheter

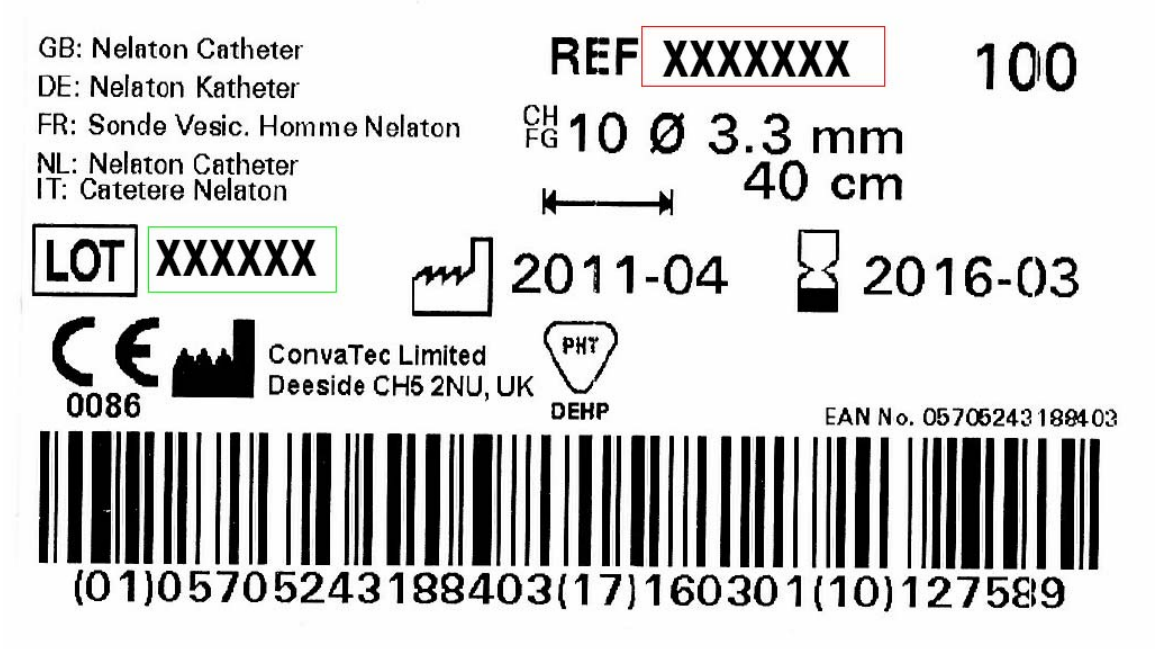


IMAGE 3A
Rectal Catheter

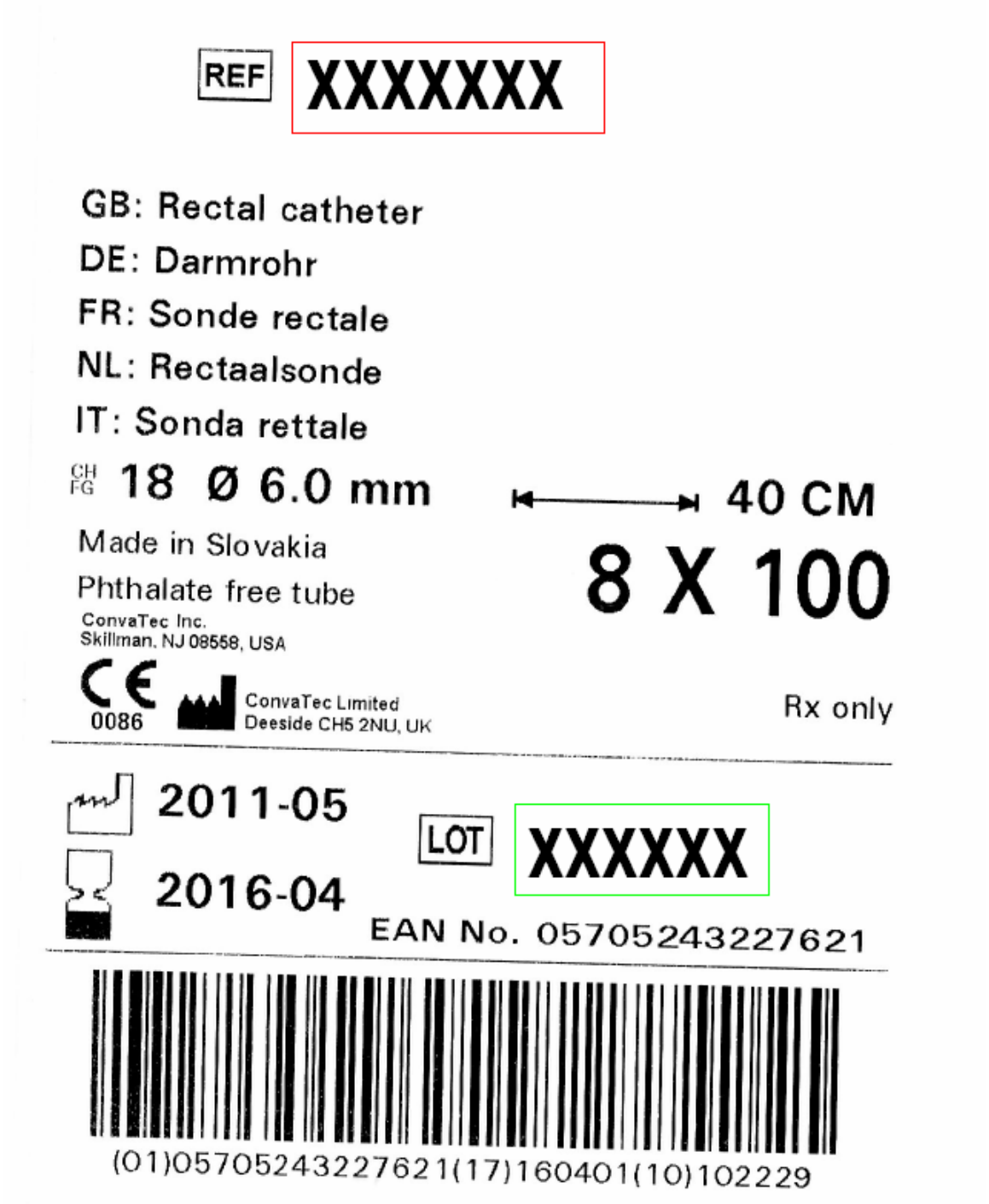


IMAGE 3B
Rectal Catheter

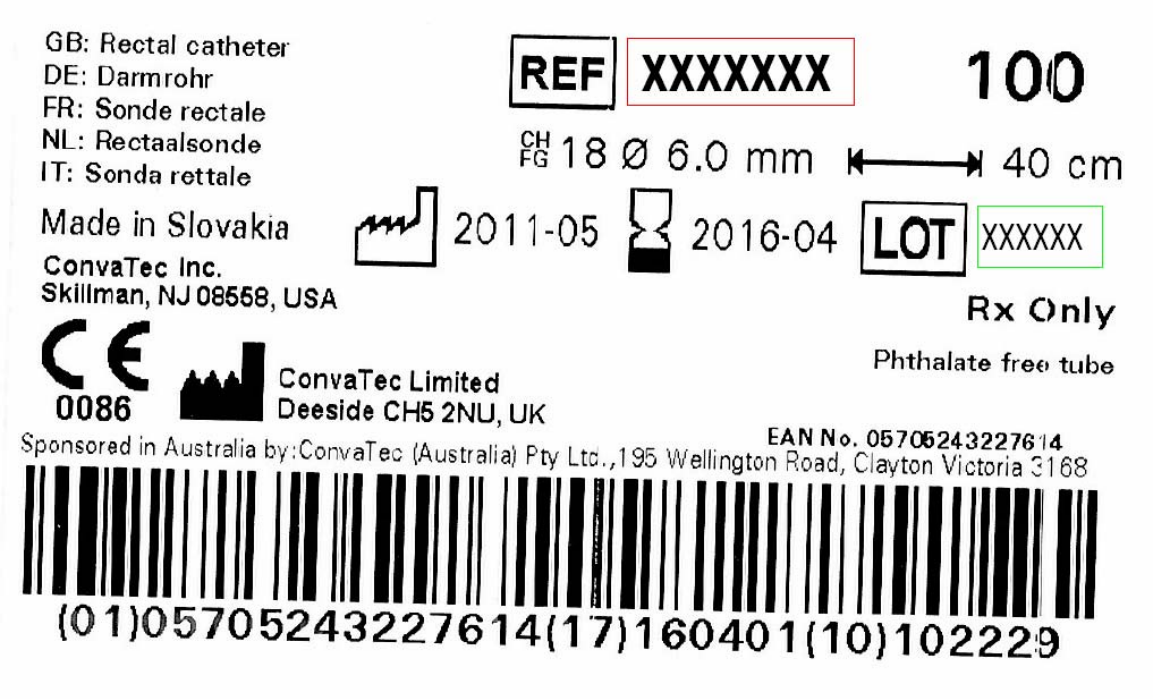
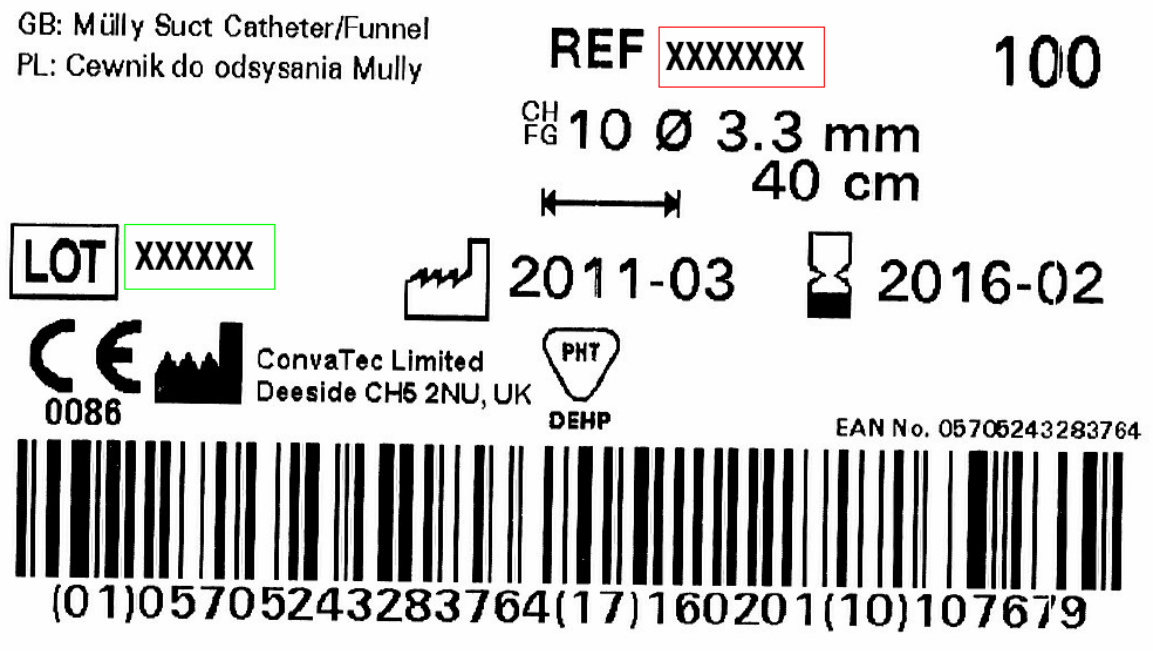


IMAGE 4A
Mülly suction catheter

IMAGE 4B
Mülly suction catheter



All affected device reference numbers and lot numbers are listed on page 13 of this Field Safety Notice.

Instructions on action to be taken by the distributor:

Our records show that you have taken delivery of the affected products. Please follow the steps below:

1. Please examine both the enclosed questionnaires and immediately put all products you may have on hold.
2. Please forward copies of the Field Safety Notice END USERS and “Recall Questionnaire for end users” to your customers, asking them to return the affected products to you.
3. When the products and completed “Recall Questionnaire for end users” have been returned to you, please contact Unomedical to arrange for the stock to be returned and credited.
4. Please mark all returned product clearly with: “Unomedical 2011-09-CTH3 from *Your Name Here*”
5. Please also return completed “Recall Questionnaire for Distributor” and all “Recall Questionnaires for End Users” to us via Fax/ E-mail.

Transmission of this Field Safety Notice:

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.

The relevant National Authorities have been advised about this Field Safety Corrective Action.

Unomedical apologises for any inconvenience this may cause and requests that you share this notice with all relevant customers/users. If you have any questions, please contact your distributor or local Unomedical/ConvaTec representative.

Contact reference person relating to this letter:

UK Contact

Name: Jo Snead
UK Customer and Services Distribution Manager
Address: ConvaTec Ltd.
Deeside Industrial Park
Deeside
Flintshire
CH5 2NU
UK
Tel: +44 (0) 1244 584 285
Fax: +44 (0) 1244 284 892
E-mail: jo.snead@convatec.com

European Contact

Name: Bente Blauenfeldt
Distribution Analyst
Address: Unomedical A/S
Birkerød Kongevej 2
3460 Birkerød
Denmark
Tel: + 45 48 10 30 56
Fax: + 45 48 10 30 00
E-mail: bente.blauenfeldt@convatec.com

AFFECTED DEVICE LISTING

Catheter Description	Product Code (Ref)	Lot Number
Female CH10	02015181	411050
		416231
	02015179	414990
	02015182	412514
		414576
		416067
		417758
	02015183	415776
		418136
	02058022	414600
		417208
		418254
	02058419	417346
		418256
	02058559	417210
	011.10.020	413096
		414999
Female CH12	02016022	411682
		413216
		414578
		416069
	02016179	411564
		415237
	02016181	412324
		414190
		416918
	02016182	412515
		414388
		414582
		416070
		417759
	02016183	411692
		414584
		417198
	02016185	414191
		416920
	02016559	417199

		412517
		414586
		416072
		417200
	02017022	418250
	02017179	414992
		414192
		415484
		416921
	02017181	418185
		412518
		414389
		414589
		414590
		416073
		417761
	02017182	418251
		415778
	02017183	417202
	02017185	416923
	02017419	417345
		417205
	02017559	418769
		413887
Female CH14	011.14.020	415000
		411689
		414594
		416075
	02019022	417206
	02019179	414993
		412315
		415488
	02019181	417370
		411693
		412521
		414390
		416076
	02019182	417763
		415780
		418138
	02019183	419423
Female CH16	02019419	414597
Female CH18	02020181	417371

Nelaton CH10	01007022	417185
	01007183	417186
	01007184	418236
	01007242	418755
	01007559	417188
Nelaton CH12	01008181	417364
	01008182	417365
	01008183	417190
		418133
	01008184	416559
Nelaton CH14	01009022	416061
	01009183	415772
Nelaton CH18	01015419	418242
Rectal CH 18	14003182	414762
Suction Mully CH10	05076181	417378
	05076182	419814
	05076184	419452

RECALL QUESTIONNAIRE FOR DISTRIBUTORS

Consignee of the Unomedical device:

Name: _____
Address: _____

The following devices have been forwarded to you:

Invoice #	Sales Order #	REF	Lot No	Number Delivered

The consignee confirms (please, tick off as applicable):

_____ that none of the devices mentioned above are in my possession.

_____ that some of the devices mentioned above remain in my possession.
They will be returned as per the instructions given by Unomedical.

Number/ Lot to be returned: _____ pieces

_____ that some devices have been sent to the following customers:

NAME:	ADDRESS:	QUANTITY:

_____ that these customers will be contacted to ensure that they are following the instructions submitted to them.

_____ that I request Unomedical to contact these customers.

_____ _____ _____
NAME (CAPITAL LETTERS) AND POSITION SIGNATURE DATE

_____
ADDRESS

This form has been forwarded by a representative of Unomedical:

_____ _____ _____
NAME SIGNATURE DATE