LEONHARD LANG
Connect with Quality

To:

XXX

From:

Leonhard Lang GmbH
Archenweg 56
A-6020 Innsbruck

Innsbruck, August 7, 2017

IMPORTANT SAFETY NOTIFICATION

Reference: CAP-17-0091

Reference authority: BASG Bundesamt für Sicherheit im Gesundheitswesen, Traisengasse 5, 1200 Wien, Österreich

Product trade name: Defibrillation Electrode SKINTACT DF59N
Defibrillation Electrode SKINTACT DF59NC

Required action: Destruction of affected products

Target group: Dealers, Distributors and Final Customer

Dear Ladies and Gentlemen,

This letter is to inform you of the recall of the articles and the concerned lot numbers listed below:

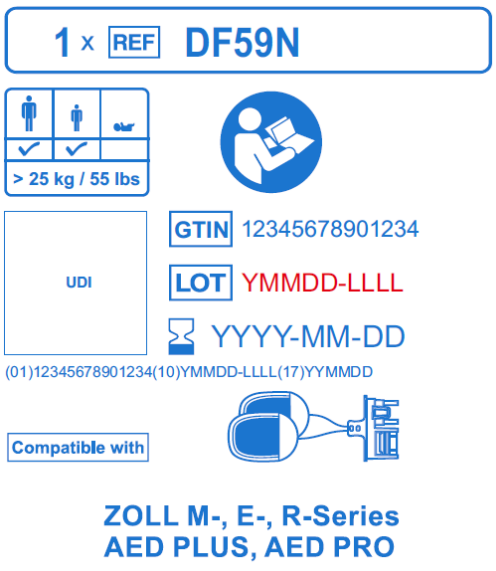
Product trade name:	Defibrillation Electrode SKINTACT DF59N
REF:	DF59N
Article No. Leonhard Lang:	50643
Lot numbers:	41029-0770 41219-0778 50403-0772

Product trade name:	Defibrillation Electrode SKINTACT DF59NC
REF:	DF59NC
Article No. Leonhard Lang:	50644
Lot numbers:	40906-0972 41203-0973 50116-0975 50211-0974 50402-0974 50527-0974

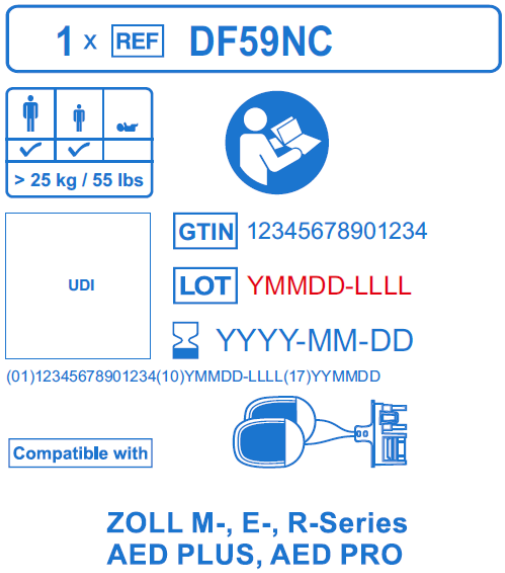
Identification of the lot number on the product packing:

The lot number could be typified on the pouch by the symbol LOT. Following this symbol the lot number is labelled (here highlighted in red).

Sample of the affected type **DF59N**



Sample of the affected type **DF59NC**



The form **Safety Notification and Immediate Actions** lists the affected lot numbers and the quantities shipped to you.

Please read this letter carefully and follow the steps in section 2 of this letter.

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1. Description of the defect

Summary: During an investigation triggered by customer feedback, it was discovered that it can be aggravated to connect some lot numbers of these defibrillation electrodes with the defibrillator ZOLL AED PLUS. As a consequence, it may happen that the user does not connect the electrodes with the defibrillator in an emergency situation.

Conditions for the occurrence of the issue: Use of defibrillation electrodes DF59N oder DF59NC with the stated lot numbers in defibrillator ZOLL AED PLUS.

Potential risk: There is a risk that these electrodes will be connected with the defibrillator ZOLL AED PLUS only with delay or not at all. This may cause a situation in which a patient who is in a life-threatening condition and requires a defibrillation shock, cannot be treated in good time.

Safety information: With this letter, Leonhard Lang informs you of the fact that this safety notificaton will also be forwarded to the competent authorities. Please note that under existing legislation you are obliged to comply with the requirements of this recall action.

Note: As a precaution, all electrodes of the affected lot numbers must be recalled, although they have no connecting problem and therefore no safety risk with ZOLL M-, E-, R- Series and AED PRO devices.

2. Actions and timeframe of the recall

a.) Please read this safety notification carefully. If there are any questions or you are unable to implement the required actions, please urgently contact the organization, which has sent you this safety notification.

b.) Please ensure in your organization that all users and other persons concerned are aware of this important safety notification and that all affected products in stock are quarantined.

c.) Please contact the organization which has sent this safety notification to you and coordinate the required quantity of replacement electrodes immediately. As soon as you have received replacement electrodes, all affected products in stock must be destroyed. Please let us know, no later than **August 25, 2017** how many of the affected products you have destroyed, used / consumed and distributed to customers. Please use the form **Safety Notification and Immediate Actions** for the confirmation.

c1.) If you have not distributed any affected products to your customers and if you have completed and returned the form **Safety Notification and Immediate Actions** to us, your actions are completed. Otherwise continue with section d.).

d.) If you have distributed any affected products to customers, please forward a copy of this **Safety Notification** and the forms **Safety Notification and Immediate Actions** and **Customers' Responses Summary** to them.

Please note that you need to amend the table in **Safety Notification and Immediate Actions** (columns 1 to 3) for each customer individually. Enter all affected lot numbers and quantities they have received from you and replace the adress (page 2) with your adress.

e.) For each lot number, please add up all your customers' responses from the returned forms **Safety Notification and Immediate Actions** and **Customers' Responses Summary** and enter the totals in the table in your form **Customers' Responses Summary**. The totals should add upp to the number of products you had shipped to your supplier. Sign the completed form and return it to the return adress indicated at the end of that form, no later than **October 27, 2017**.

f.) If the required data from your customers are not complete, you are obligated to actively take actions to ensure, you receive the outstanding data.

We ask you to keep the originals.

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3. Replacement product

As substitute for both recalled products we provide the article:

Handelsbezeichnung des Produkts:	**Defibrillationselektrode SKINTACT DF59NC**
REF:	DF59NC
Artikel-Nr. Leonhard Lang:	50644

List of annexes:

- Safety Notification and Immediate Actions
- Customers' Responses Summary

We apologize for any inconvenience caused by this issue. However, to allow patients and users to safely utilize our products, these measures have to be taken immediately. We assure you that safety and quality are our first and foremost priorities. Please do not hesitate to contact our sales staff with any questions you may have.

Yours sincerely,

[redacted]

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Appendix A

Safety Notification and Immediate Actions

a. We have read and understood the safety notification from August 7, 2017.

b. We confirm that within our organization all users and other persons concerned have been informed about the content of the safety notification.

c. Please complete the table below by entering the quantities you have destroyed, used / consumed and distributed to customers (see columns highlighted light blue).

1	2	3	4	5	6
Product / Article	**Lot Number**	**Quantity received by your company**	**Quantity destroyed**	**Quantity used / consumed**	**Quantity distributed to customers**

We confirm that we have destroyed all affected products we had in stock.

d. If you have distributed any affected products to customers (see table above, column 6):

We confirm that we have notified all customers who purchased / received affected products in writing and without delay of this safety notification and of the necessary corrective action by forwarding them the documents:

- Safety Notification
- Appendix A: Safety Notification and Immediate Actions
- Appendix B: Customers' Responses Summary

e. If you have distributed any affected products to customers (see table above, column 6):

We understood that report "Customers' Responses Summary" has to be returned by October 27, 2017.

Remark:

Recall CAP-17-0091

Please sign the completed form and return a copy by e-mail, fax or mail to the organization indicated below no later than **August 25, 2017**.

Return Address:

Leonhard Lang GmbH
Attn. xxx
Archenweg 56
Austria

Phone: +43 (0)512 33425-xxxx
Fax: xxx
E-Mail: xxx

Thank you for your cooperation!

Company Name:			
Address:			
City:		State/Zip Code:	
Family Name:		First Name:	
Phone:		Fax:	
E-Mail:			

Date / Signature:

Company Stamp:

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Appendix B

Customers' Responses Summary

a. We confirm that we received the forms "Safety Notification and Immediate Actions" (Appendix A) and "Customers' Responses Summary" (Appendix B) from all customers that purchased / received products with the affected lot numbers from us.

b. Please add up all **your customers' responses** from the returned forms (see Appendix A and B) for each lot and enter the totals in the table below.

1	2	3	4	5
Product / Article	**Lot Number**	**Quantity distributed to customers by us**	of these: **Quantity destroyed by customers**	of these: **Quantity used / consumed by customers**

c. We confirm that we will retain the signed answering forms of our customers.

Remark:

Please sign the completed form and return a copy by email, fax or mail to the organization indicated below no later than **October 27, 2017**.

Return Address:

Leonhard Lang GmbH
Attn. xxx
Archenweg 56
Austria

Phone: +43 (0)512 33425-xxxx
Fax: xxx
E-Mail: xxx

Thank you for your cooperation!

Recall CAP-17-0091

Company Name:			
Address:			
City:		State/Zip Code:	
Family Name:		First Name:	
Phone:		Fax:	
E-Mail:			

Date / Signature:

Company Stamp: