



MDR-FSN-GLOBAL

Urgent Safety Information

Urgent Safety Information

Kind of Measure: Recall

Trading name of the concerned medical device: BeeSana Mullkompresse; 5x5 cm, 8-fach, REF1043

Date: 2018-07-09

Sender:

Meditrade GmbH

Medipark 1

83088 Kiefersfelden

Recipient:

Users

Identification of the concerned medical device:

BeeSana Mullkompresse; 5x5 cm, 8-fach, REF1043

Batch number: LOT 7855-1406

Description of the Problem including the investigated reason:

- While printing of the variable data, an input mistake was not recognized
- The wrong printed variable date is only on the innermost packaging (pouch)
- Printed expiry date: 2109-06
- Correct expiry date: 2019-06
- Using of the products after 2019-06 should be avoided, because there is a risk, that the product is no longer sterile

Which measures should be done by the recipient:

- Control if you have products of the batch LOT No.7855-1406 in the warehouse
- If yes, please sent us the products back, so that we can exchange the products
- Please send us the confirmation of receipt back



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Forwarding of the described information

Please assure that within your organization, all the users of the above mentioned product and other persons who should be informed about the issue, the **urgent safety information** are receipt.

If you have forwarded products to third persons, please forward a copy of this information or inform the mentioned contact person underneath.

Please maintain this information, as long as the measurement is closed.

The responsible authorities have got a copy of this "Urgent Safety information".

Contact person:

Meditrade GmbH

Departement Quality Assurance

Frau Anja Birner

Medipark 1

83088 Kiefersfelden

Tel.: 08033 9760-25

Fax: 08033 9760-60

Email: reklamation@meditrade.de

A black rectangular box used to redact the signature of the contact person.

signature

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Confirmation of receipt about the urgent Safety Information concerning the expiry date BeeSana Mullkompresse of 09.07.2018

Please fill out this confirmation of receipt completely and tick the according fields. **Please inform us even in the case, when you don't have any longer one of the listed medical devices left in your stock.**

Medical device: BeeSana Mullkompresse 5x5 cm 8-fach

Article number: REF 1043

LOT/ Batch No.: 7855-1406

- ☐ We herewith confirm the receipt of the urgent Safety Information and we will send _____ pieces of the concerned product for exchange back.
- ☐ We herewith confirm the receipt of the urgent Safety Information and have destructed _____ pieces of the concerned product.
- ☐ We herewith confirm the receipt of the urgent Safety Information and don't have any of the concerned products left in our Organization.



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Urgent Safety Information

Name of the facility:

Name of the Department:

Name of the contact person:

Street:

Postcode:

City:

Tel.:

Fax:

Date:

Signature:

Please send the response to following address:

Meditrade GmbH

Medipark 1

83088 Kiefersfelden

reklamation@meditrade.de

or via FAX to

Faxnumber: 49 (0) 8033 9760-60

Thank you very much for your cooperation.