MEDTRON AG | Hauptstraße 255 | 66128 Saarbrücken

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66128 Saarbrücken

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Internet www.medtron.de

Field Safety Notice

regarding restriction of the patient group to patients ≥ 10 kg for consumables from MEDTRON AG

Date: 2025-05-20

Type of measure: advice: restriction of patient group

Addressees: user, operator, distributor

Affected medical devices / Identification of affected medical devices:

All consumables from MEDTRON AG

Description of the problem including the identified cause:

Currently the consumables from MEDTRON AG do not provide evidence that they fulfill the requirements for ethylene oxide residuals according to DIN EN ISO 10993-7:2022 (Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals) for use in special patient populations, in particular children, infants, neonates and premature infants.

There might be a health risk for patients < 10 kg due to increased ethylene oxide residuals.

Thus, the use of the consumables is restricted to patients ≥ 10 kg.

The instructions for use (IFU) of all affected products will be updated regarding the restricted patient group and will be included with the products and published on the website of MEDTRON AG within the scope of a product update in the next months. The products can still be used with the current instructions for use for patients ≥ 10 kg.

Vorstand: Markus Bappert
Aufsichtsratsvorsitzender: Prof. Dr. Dr. Günter Brill
Amtsgericht Saarbrücken | HRB 13752 | Ust. –Id. –Nr. DE 138167008

Deutsche Bank AG | Kto. –Nr. 0508804 | BLZ 590 700 00
BIC (SWIFT-CODE): DEUTDE5M555
IBAN DE32 5907 0000 0050 8804

Bank 1 Saar eG | Kto. –Nr. 996 430 05 | BLZ 590 900 00
BIC (SWIFT-CODE): SABADE5S
IBAN DE06 5919 0000 0099 6430 05

Measures to be taken by the user and operator:

Please do not use the products anymore for patients < 10 kg.

If the products have already been used no further measures are required.

The products can still be used for patients ≥ 10 kg and no further measures are required.

Forwarding the information described in this letter:

Please make sure that all users of the above-mentioned products in your company and other persons to be informed take note of this "Field Safety Notice".
If you have supplied the products to third parties, please forward a copy of this information or inform the contact person mentioned below.

Please keep this information at least until the measure has been completed.

The German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte) has received a copy of this " Field Safety Notice".

Acknowledgement of receipt:

Please return the attached "Acknowledgement of receipt of the Field Safety Notice dated 20 May 2025" as soon as possible but no later than 20 June 2025 to the following e-mail address:

Customers that buy consumables directly from MEDTRON AG:	vigilance@medtron.com
Customers that buy consumables from a distributor:	E-mail address of your distributor

Contact person MEDTRON AG:

Manuel Warth, PRRC (Person responsible for regulatory compliance)
Tel.: +49 681 97017 41 / e-Mail: vigilance@medtron.com

If you have any further questions, please do not hesitate to contact us.

Best regards

Manuel Warth
PRRC (Person responsible for regulatory compliance)

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Acknowledgement of receipt of Field Safety Notice

Please complete this form and return it as soon as possible but not later than 20 June 2025 to the following e-mail address:

Customers that buy consumables directly from MEDTRON AG:	vigilance@medtron.com
Customers that buy consumables from a distributor:	E-mail address of your distributor

☐ We hereby confirm that we have received and understood the Field Safety Notice dated 20 May 2025 concerning the restriction of the patient group for consumables from MEDTRON AG. The Field Safety Notice has been communicated within our organization.

Name of company / organization	
Street:	
Zip code:	
City:	
Country:	
Phone number:	
E-Mail-Address:	
Name of contact person:	
Date:	
Signature:	