**Urgent safety information**

RECALL

of

NETWORK-ISOLATOR Cat.6A FOR HEALTHCARE

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23.09.2024

**Sender:**

EFB-Elektronik GmbH,

**Addressee:**

To all customers and users

**Identification of the affected medical devices:**

NETWORK-ISOLATOR Cat.6A FOR HEALTHCARE:

| Item no. | Description | Model |
|---|---|---|
| NET-ISOADAPRJ45 | Network-isolator Cat.6A for healthcare jack / jack | jack / jack |
| NET-ISOKABELRJ45 | Network-isolator Cat. 6A for healthcare plug / jack with cable 0,15 m | plug / jack |

**Description of the complaint:**

Network isolators are galvanic isolators for Ethernet-based networks. Medical electrical devices (ME devices) sometimes do not have their own galvanic isolator. A network isolator is then required to operate the ME device. A network isolator is also required when connecting a medical device to a non-ME device (e.g. a printer). In the medical field, network isolators are used to protect users and patients from leakage currents.

The reason for implementing this corrective measure is the lack of conformity of the above-mentioned product as an "accessory" with regulation (EU) 2017/745. We have not yet been aware of any incidents or serious incidents in connection with the above-mentioned product, but the affected products should not be used any further due to the lack of conformity.

**What measures must customer / user take?**

If you have already received the above-mentioned product and are using it in a medical environment, we ask you to stop using it immediately.

Please return the affected products to the following address:

**EFB Elektronik GmbH**
**Logistik Zentrum**
**Abteilung TSQ**
**Röntgenstraße 13**
**32052 Herford**

We will of course refund the purchase price in full. We will use the same payment method you used to make the refund. If you would prefer a different method of payment, please let us know.

**Sharing of the information described here:**

Please ensure in your organization that all users of the above-mentioned products and other persons to be informed are aware of this **urgent safety information**. If you have given the products to third parties, please forward a copy of this information or inform the contact person specified below.

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

The German Federal Institute for medicine and medical devices has received a copy of this "urgent safety information".

**Contact person:**

**Mr. Ingo Lopmann**
**Mailto: i.Lopmann@efb-elektronik.de**
**Mobil: +49 160 9052 1199**
**Monday to Friday from 9:00 to 16:00**

We regret the inconvenience this recall may cause you and thank you for your understanding and co-operation.