

## Field Safety Notice

Dear Ladies and Gentlemen,

For Memmert GmbH + Co. KG, the satisfaction of the users of our products is our top priority. By continuously monitoring the safety and quality of our products in the field, we are always striving to improve our products.

### Description of the situation

In the period from 01.01.2013 up to and including 04.04.2023, medical devices were imported into Switzerland in which an unauthorized power cord is installed on the device side. These power cords are equipped with a non-partially insulated power plug, which no longer represent the state of the art due to the entry into force of the standard SEV 1011:2009 and whose introduction into Switzerland is no longer permissible.

### Which devices are affected?

After checking all devices in the field, it was determined that the devices of the following serial numbers are affected:

| Description | Serial number | Description | Serial number | Description | Serial number |
|-------------|---------------|-------------|---------------|-------------|---------------|
| INC108med   | O112.0286     | INC153med   | O215.0253     | INC153med   | O218.0004     |
| INC108med   | O113.0069     | INC153med   | O215.0282     | INC153med   | O218.0005     |
| INC108med   | O113.0180     | INC153med   | O215.0283     | INC246med   | O316.0037     |
| INC108med   | O115.0030     | INC153med   | O215.0284     | INC246med   | O316.0038     |
| INC108med   | O115.0040     | INC153med   | O215.0293     | INC246med   | O317.0027     |
| INC108med   | O115.0053     | INC153med   | O215.0294     | INC246med   | O313.0017     |
| INC108med   | O115.0180     | INC153med   | O215.0295     | INC246med   | O313.0031     |
| INC108med   | O116.0025     | INC153med   | O215.0285     | INC246med   | O313.0032     |
| INC108med   | O116.0033     | INC153med   | O215.0286     | INC246med   | O313.0099     |
| INC153med   | O212.0284     | INC153med   | O215.0287     | INC246med   | O313.0100     |
| INC153med   | O212.0286     | INC153med   | O215.0288     | INC246med   | O313.0101     |
| INC153med   | O213.0020     | INC153med   | O215.0289     | INC246med   | O314.0098     |
| INC153med   | O213.0023     | INC153med   | O215.0290     | INC246med   | O314.0115     |
| INC153med   | O213.0128     | INC153med   | O215.0291     | INC246med   | O315.0059     |
| INC153med   | O213.0140     | INC153med   | O215.0292     | INC246med   | O315.0060     |
| INC153med   | O214.0002     | INC153med   | O215.0296     | INC246med   | O316.0031     |
| INC153med   | O214.0003     | INC153med   | O215.0297     | INC246med   | O316.0032     |
| INC153med   | O214.0029     | INC153med   | O215.0299     | INC246med   | O316.0033     |
| INC153med   | O214.0112     | INC153med   | O215.0333     | INC246med   | O316.0034     |
| INC153med   | O214.0180     | INC153med   | O216.0125     | INC246med   | O316.0035     |
| INC153med   | O214.0272     | INC153med   | O217.0058     | INC246med   | O316.0036     |
| INC153med   | O215.0144     | INC153med   | O217.0059     |             |               |
| INC153med   | O215.0158     | INC153med   | O217.0072     |             |               |

All users of a Memmert device listed in this table are contacted by this letter. We will also provide you with a list of the devices that were sold by you.

**What measures are to be taken by the seller/end customer?**

1. please identify all affected devices by their serial number
2. the affected equipment may continue to be used until the power cord with power plug is replaced, provided due consideration is given to the risk of electric shock from touching the uninsulated power plug pins when connecting and disconnecting the power plug.
3. the mains cables must be replaced by a competent service technician with compliant mains cables in accordance with the enclosed installation instructions.
4. it is imperative that you complete the enclosed response form for the Field Safety Notice and send it in signed form to the contact address given there.

**Measures taken by Memmert GmbH + Co. KG**

The design of the affected device types has been adapted to conforming mains cables. Memmert GmbH + Co. KG will send you conforming mains cables for the modification.

**Passing on this information**

Please ensure that this notice is passed on in your organization to all affected users and other persons (also outside your organization) who may be affected by this safety notice. In addition, please retain this information until the above actions to be taken have been executed.

**Contact Person**

If you have any questions about this notice or need additional information, please contact:

Memmert GmbH + Co. KG  
Äußere Rittersbacher Straße 38  
D-91126 Schwabach

Dr. Jan Wittstatt  
Telefon: +49 9122 925 279  
E-Mail: [jwittstatt@memmert.com](mailto:jwittstatt@memmert.com)

We apologize for any inconvenience caused by the security message.



Dr. Jan Wittstatt

PRRC



## Field Safety Notice Customer Reply Form

| 1. Field Safety Notice (FSN) information |                                 |
|--|---------------------------------|
| FSN Reference number*                    | FSN-23001                       |
| FSN Date*                                | 10.05.2023                      |
| Product-/ Device name*                   | INC108med/ INC153med/ INC246med |
| Product Code(s)                          |                                 |
| Batch/Serial Number (s)                  |                                 |

| 2. Customer Details                    |  |
|--|--|
| Account Number                         |  |
| Healthcare Organisation Name*          |  |
| Organisation Address*                  |  |
| Department/Unit                        |  |
| Shipping address if different to above |  |
| Contact Name*                          |  |
| Title or Function                      |  |
| Telephone number*                      |  |
| Email*                                 |  |

| 3. Customer action undertaken on behalf of Healthcare Organisation |   |  |
|--|---|--|
| <input type="checkbox"/>   | I confirm receipt of the Field Safety Notice and that I read and understood its content.                    |  |
| <input type="checkbox"/>   | I performed all actions requested by the FSN.   |  |
| <input type="checkbox"/>   | The information and required actions have been brought to the attention of all relevant users and executed. |  |
| <input type="checkbox"/>   | Other Action (Define):  |  |
| <input type="checkbox"/>   | I do not have any affected devices.   |  |
| <input type="checkbox"/>   | I have a query please contact me (e.g. need for replacement of the product).                                |  |
| Print Name*  |   |  |
| Signature*   |   |  |
| Date*  |   |  |

| <b>4. Return acknowledgement to sender</b>      |   |
|---|---|
| Email   | jwittstatt@memmert.com  |
| Customer Helpline                               | +499122/925-0   |
| Postal Address                                  | Äußere Rittersbacher Straße 38, D-91126 Schwabach               |
| Web Portal                                      | <a href="https://www.memmert.com/">https://www.memmert.com/</a> |
| Deadline for returning the customer reply form* | 16.06.2023  |

Mandatory fields are marked with \*

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.