

URGENT SAFETY INFORMATION

avateramedical GmbH
 Ernst-Ruska-Ring 23
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 Germany
 30. November 2022

To: Representative for Medical Device Safety, Medical Technology

Recall concerning sterile products

This document contains important information for your product. Please ensure that all potential users in your healthcare facility are made aware of this safety notice and the recommended actions. Please retain this document for your records.

Products concerned	<i>Affected regions:</i> Germany, Greece, Hungary <i>Affected products:</i> see Annex
Safety issue	Sterile products with insufficient labeling were delivered to the customer with a special release label.
Measures required	Please, check your stock of sterile products of avateramedical GmbH according to the attached product list and enter the remaining quantity of products. Please return the filled product list together with the acknowledgement of the receipt of this information. If the product batches mentioned in the attachment are in your possession, we hereby instruct you to no longer use these products and to have them available for collection. Please contact [REDACTED] (e-mail: [REDACTED]@avateramedical.com, phone: [REDACTED]) to arrange the collection of the products.
Contact	For questions regarding this corrective action or to identify the products concerned, please contact your local sales or service representative or the Technical Support Service Center. Tel. +49 3641 2724 300 / prrc@avateramedical.com.

avateramedical confirms that this notification has been sent to the competent national authority.

In this context, we would like to point out that the preservation of a high level of safety and quality is our primary priority.

We thank you for your cooperation and apologize for any inconvenience caused.
 Please also refer to the following page to acknowledge receipt of this safety information.



SVP CR, **avateramedical**

NOTIFICATION CONCERNING A MEDICAL PRODUCT

Please send the completed acknowledgement of receipt by e-mail to: prrc@avateramedical.com

Please complete this form and return it to **avateramedical** immediately upon receipt, but no later than 09. December 2022.

- I acknowledge receipt and comprehension of the enclosed notice about the medical device. I further acknowledge that responsible personnel have been informed and have taken or will take appropriate action in accordance with this notice.

Healthcare facility: _____

Street and number: _____

Postal code and city: _____

Name (print letters): _____

Position: _____

E-Mail address: _____

Phone number: _____

Signature: _____

Date (DD.MM.YYYY) _____