



Dahlewitz, 30.03.2023

Field Safety Notice

Dear Customer,

There is a product defect in the following product and we request that you implement the measures described. Please inform us in writing about the receipt of these safety instructions and the implementation of the measures at regulatory@medipan.de.

Product name : Medizym anti-IA2 M

REF : 3506

LOT : 22350602/1

Fault description

The certificate of analysis enclosed with the product contains incorrect information on the sample dilution to be used for machine processing.

Measures

For endusers:

Only use the described product with the certificate of analysis dated 08.03.2023, which is attached to the e-mail with which you also received these safety instructions. The file name is "MP-CA-3506-2202-1-23-03-08".

All results obtained with the faulty certificate of analysis when processing the product by machine must be withdrawn.

For distributors:

Provide each container of the described product that you continue to place on the market with the corrected certificate of analysis dated 08.03.2023, which can be found in the attachment to the e-mail with which you also received this safety instruction. The file name is "MP-CA-3506-2202-1-23-03-08".

Furthermore, inform your customers in writing about its exclusive use and request the end user to withdraw all results collected with the faulty certificate of analysis when processing the product by machine.