

URGENT FIELD SAFETY NOTICE

Missing engraving and changed marking of Ethanol Standard FS 0.5 mg/mL

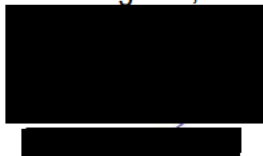
Date	2022-12-16	
Product / Lot	Ethanol Standard FS 0.5 mg/mL	Product code: 1 0890 99 10 349 Lot: FN09152001 Kit lot: 60152111
Explanation	For above mentioned kit lot of Ethanol Standard FS 0.5 mg/mL the engraving on the ampoules mentioning important product information is missing. In addition, the marking on the neck of the ampoule has been changed from an originally used white dot to a brown ring. However, it is ensured that the ampoules contain the ethanol standard with the concentration of 0.5 mg/ml. For this reason, the product can be used as usual. The above mentioned changes affect only this kit lot.	
Impact on patient results	None.	
Measures	Please ensure that the non-engraved ampoules are not mixed up after removal from the kit. Please inform all users of the affected product immediately.	

DiaSys has announced this field safety notice to the relevant authorities of the European Union. Customers outside the EU are asked to handle necessary announcements to authorities in their countries.

Under current regulations we are obliged to provide a complete chain of evidence of all corrective measures for our products. For this reason, we would like to ask you to fill in and sign the attached confirmation that you have received and communicated this information to all concerned customers. Please send it back by fax or as scan until 2022-12-31.

Please accept our sincere apologies for the inconvenience caused. In case you have any questions, please do not hesitate to contact us.

Best regards,



Product Management