Customer
Hospital
City
Postal code
Country
Attn.: XXX

*safe*PICO A aspirating blood syringe

Dear Customer

This is a follow-up to the previous communication, which was distributed this October (please see "Recap of previous communication, distributed this October" on page 2 of this letter).

The issue has been resolved and the risk for the patient has been eliminated
Radiometer is pleased to inform you that effective countermeasures have been taken to eliminate the issue related to the sterile barrier system for the *safe*PICO A aspirating blood syringe, 957-204.

The countermeasures are implemented in *safe*PICO A aspirating blood syringe manufactured from 2024.11.08. The first Lot produced is CZ01.

Hence, the *safe*PICO A aspirating blood syringe is now available for ordering.

Your action
Radiometer kindly requests you to complete the Recall Response Form (on the last page of this letter) and return it to your Radiometer representative within two weeks of receiving this letter.

Your help is appreciated
If you are not the end-user of the affected product, please ensure that this letter is distributed to the final end-user.

If you have any questions, please contact your Radiometer representative.
Radiometer sincerely apologizes for the inconvenience this situation may have caused you.

Best regards,
<State Radiometer distributor name>

Recap of previous communication, distributed this October:

Background
Radiometer has become aware of an issue with the *safe*PICO A aspirating blood syringe. The issue relates to the sterile barrier system for the product.

For this reason, Radiometer kindly requests you to stop using the affected product with immediate effect.

Risk for the patient
The described error may potentially result in bacterial bloodstream infection. The bloodstream infection may be asymptomatic but may also progress to sepsis or life-threatening septic shock. Immunosuppressed patients are at particular risk.

Affected product
All Lots of the *safe*PICO A aspirating blood syringe, 957-204.

For EU Countries only the following is to be included in translated letter:

EU Basic UDI-DI: 57006900067N9

(UDI = Unique Device Identifier – DI = Device Identifier)

Recall Response Form

Concerning:

_safe_PICO A aspirating blood syringe

☐ I have received the customer information letter stating that the issue has been resolved, the risk for the patient has been eliminated, and the *safe*PICO A aspirating blood syringes are available for ordering.

Hospital Name:	
Your Name:	
Date:	
Signature:	
Email Address:	