stratec

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Manufacturer's notice on **"GEMINI"** and **"GEMINI** Combo"

DearXXX,

Based on the feedback of one of our sales partners and our subsequent analysis, we would like to inform you with this letter about a potential risk of incorrect use of our instruments "GEMINI" and "GEMINI Combo".

The software architecture of the "GEMINI" and "GEMINI Combo" instruments is designed to share identical reagents within a worklist. The so-called "Alternate Bottle Function" is intended to use further bottles of the same reagent type, if the filling level of the current bottle is not sufficient to complete a given test run.

As described in the **"GEMINI"** and **"GEMINI** Combo" lnstructions for use (chapter 4.6 "lot specific values"), the system does not distinguish between identical reagents of different lots or other specific lot parameters, unless this is prevented by a separate and unique reagent definition (by reagent name) in the corresponding reagent database.

lf the optional "Reagent Check" function is not activated in the software, the instrument intentionally uses bottles of the same reagent type, which may come from different lots, if applicable. lf such setup to use the same reagent of different lots is explicitly excluded in the package insert of your assay an impact on the final test result cannot be completely eliminated.

Therefore, if your reagents do not allow for interchangeable lots we recommend to always use the "Reagent Check" function to prevent insufficient reagent volume triggering the use of further bottles of the same reagent potentially of different lots.

As part of our ongoing effort to improve the application of our products, we are currently developing a new software version that, among others, will highlight the use of such, then optional flexibility features to the end-users.

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We ask you to ensure that this letter is forwarded to all end users. If you have passed on affected products to third parties, please make sure that this notice is passed on as well.

Please keep this notice together with your laboratory records.

STRATEC SE will officially inform the local competent authority (Bundesinstitut für Arzneimittel und Medizinprodukte, BfArM) about this letter and its relevant background.

Contact details:
Do not hesitate to contact us for any further queries.

You can contact Dr. Volker Schwaab via telephone (+49 07082 7916-189) or e-mail v.schwaab@stratec.com.

Best regards,