12/05/2025

Urgent Field Safety Notice

Dear Customers,

DH Healthcare GmbH, a Dedalus Group company, would like to bring to your attention the following issue reported to the national competent authority:

Title: Not possible to document an administration of a virtual product without package name prepared by a robot

Internal Reference: MST0099122

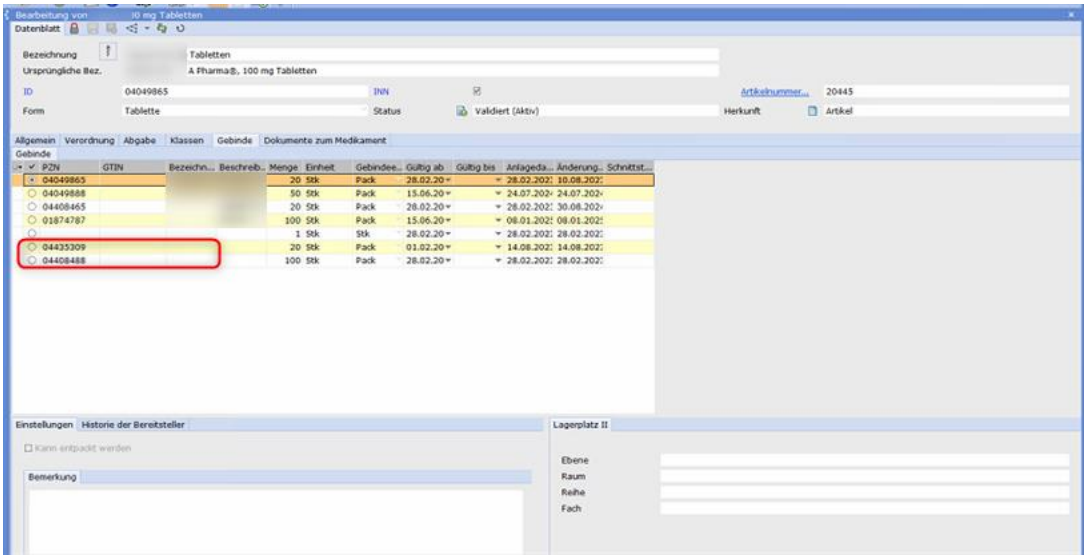
Product name and version(s) and UDI-DI:

- ORBIS Medication 03.20.05.00 and higher in ORBIS 84.42.08.00 in Germany: DH Healthcare GmbH
  UDI-DI: 4260693990026

Information:

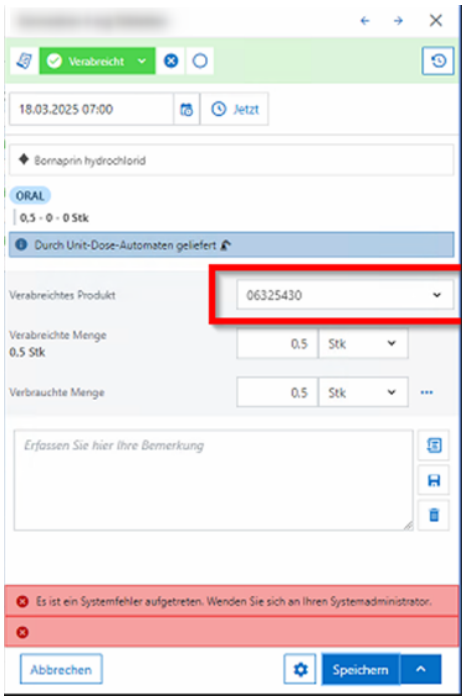
This problem can only occur for customers using a robot for dispensing purposes and the following combination:
Reorder manager (licence: ORME_REORDER) & Unit Dose reorder & MAWI & virtual product prescription (licence: ORME_VIRTUAL_PRODUCT).

Prerequisite: A virtual product is configured by the person in charge of product configuration in Medikamentenverwaltung > Qualifizierte Produkte. In the product configuration form, the configured packages normally have defined names. However, in unusual cases, it has been detected by a customer that some configured packages may have no defined name.



In this specific case, when the product is prescribed and prepared by the robot using the package with no name: when a nurse wants to register the administration of this drug, the package with no

name is selected by default in the administration screen. When the nurse wants to save the administration, an error message is displayed and the administration cannot be saved.



In the administration screen, the user can select another package from the list of available packages and, if desired, return to the default package. This action enables documentation of the administration to be saved without error.

Actions:

Actions undertaken by DH Healthcare GmbH:

- Inform the affected customers with this letter.
- Release of correction with ORBIS Medication version 03.21.00.00 or higher in ORBIS version 84.43.00.00 DACHL or higher (release planned for third quarter of 2025).

Recommended actions to be taken by the customer:

- Make sure relevant users are informed of the issue and workaround described in this safety notice
- It is highly recommended to ensure that a package name is always configured in the product configuration form.

- Install the correction when available.

Please distribute this information to all those who need to be aware of it.

Regardless of the situation described here, we would like to point out that care providers must always ensure that clinically relevant information, including prescription information, is clearly communicated and that they must use verified information (e.g., from medical devices such as monitoring systems), independent from the software being used.

It is important that you take the actions described in this safety information and acknowledge receipt of this letter.

If the above information does not apply to your hospital or if the device has been transferred to another organization, please indicate this on the attached feedback form and forward this Field Safety Notice to the respective organization.

Thank you for your careful attention to this matter and for your support.

If you have any questions on this matter, please consult our contact person:

Sincerely,

Urgent Field Safety Notice

Feedback Form

We kindly ask you to return this feedback form as soon as possible, but at the latest **within 30 days** after receipt of this letter, to the following e-mail address:
Thank you for your cooperation.

Customer / Facility (names of all affected operational facilities):	
Address:	
Reference	MST0099122 - Not possible to document an administration of a virtual product without package name prepared by a robot
Product reference:	ORBIS Medication
Name (contact person)	
Position	
Phone number	
Date	
Signature	

☐ I confirm that I have received and understood the safety information.

☐ The safety information does not apply to my facility.

☐ The device was transferred to another organization.

Name and address of the other organization: _____

☐ Please update our contact information as follows:

Customer / Facility:

Address: