
Urgent Field Safety Notice
Oral Hygiene 4 – Large Pack (Orange) non-sterile
RML101-432 – W485554
NCR 2020-0202
Notification of Labelling Error

Date: 9th October 2020

Attention:

Customers who have received Batch W485554 of Rociale Pack Reference RML101-432, Oral Hygiene 4 – Large Pack (Orange) non-sterile

Details on affected devices:

The only products affected by this Field Safety Notice are Batch W485554 of Rociale Oral Hygiene 4 – Large Pack, Ref: RML101-432.

Description of the problem:

The case label for this batch of RML101-432 bears the correct product information, however, the packs inside the cases have been mislabelled as RML101-423. Rociale does not have a product with the code RML101-423 so there is no possibility of mix up with an alternative product.

Action to be taken by Customer:

There is no impact on the performance or safety of the product and any products currently in stock at customer premises may be used as intended.

Rociale does not require any further action to be taken by the customer, other than acknowledgement of receipt of this Field Safety Notice.

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the affected batch has been transferred.

Please transfer this notice to other organisations on which this notice has an impact.

Contact reference person:

Annette Callaghan
Head of Regulatory Affairs and Sterilisation
Rociale Healthcare Limited
Cwm Cynon Business Park (North)
Mountain Ash
Rhondda Cynon Taf
CF45 4ER
UK

The undersigned confirms that this notice has been notified the appropriate Regulatory Agency. If you have any queries regarding the content of this Field Safety Notice, please email annette.callaghan@rociallehealthcare.com.



Annette Callaghan
Head of Regulatory Affairs and Sterilisation