



## Field Safety Notice (FSN)

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*Reflexx S.p.A.*  
REFLEXX S.P.A. UNIPERSONALE  
VIA PASSERI, 2 - 46019 VIADANA (MN)

Viadana, 27/04/2026

**SUBJECT: INFORMATION ON PRESENCE OF CEDMC IN REFLEXX N100 GLOVES.**

*Dear Customer,*

*Reflexx S.p.A., as legal manufacturer of REFLEXX N100 nitrile examination gloves, is issuing this Field Safety Notice as part of a Field Safety Corrective Action (FSCA).*

*You are kindly requested to take note of the following information.*

*Thank you for your kind cooperation,*

*Best regards*

*REFLEXX SpA*



## 1. AFFECTED PRODUCTS

**Product:** REFLEXX N100 nitrile gloves

**Lot numbers:** 2411400078

**UDI code:** 80328916307852706282407012411400078

**Intended Use:** Medical examination glove. The product may also provide protection against chemicals in accordance with applicable PPE standards.

## 2. REASON FOR FIELD SAFETY NOTICE

Following a report and subsequent investigations, it was found that REFLEXX N100 nitrile gloves contain traces of 2-cyanoethyl dimethyldithiocarbamate (CEDMC), a substance recently identified as contact allergen and not currently included in EN 455-5 list of potential allergens. In agreement with the “Low Derm” brand, CEDMC is not intentionally added during the manufacturing process. It has been verified that CEDMC most probably originates from a chemical reaction occurring during the nitrile glove production process.

**This Field Safety Notice is issued in order to inform all users of REFLEXX N100 gloves who have a known sensitivity to CEDMC about the possible occurrence of contact skin reactions.**

## 3. POTENTIAL RISK

CEDMC may cause allergic contact reactions (Type IV hypersensitivity) in sensitized individuals. Users having known sensitization for contact allergens may experience localized skin reactions. **The risk is considered limited to users with known sensitivity to CEDMC.**

## 4. ACTIONS TO BE TAKEN BY USERS

Users with known sensitivity to 2-cyanoethyl dimethyldithiocarbamate (CEDMC) are requested not to use REFLEXX N100 gloves. In addition, in the event of any skin reaction, discontinuation of use is recommended.



## 5. ACTIONS TAKEN BY THE MANUFACTURER

Reflexx S.p.A. started an optimization of the manufacturing process in order to eliminate the formation of CEDMC. In addition, Reflexx S.p.A. will update the product information (IFU) accordingly.

## 6. TRANSMISSION OF THIS FSN

This notice should be shared with all persons who need to be informed within your organization, as well as with any other organization to which REFLEXX N100 gloves have been supplied.

## 7. CONTACT INFORMATION

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