



credentis AG
Gubelstrass 24
6300 Zug
Switzerland

Date: 29.August.2025

Field Safety Notice (FSN)

Document reference: FSN_Record 00547_CR_EU_29.Aug.2025

Manufacturer: credentis AG

Trade name of the affected product: CURODONT™ Repair

Product number (UDI-DI): 7649991541050

Type of action: Advisory Notice

Attention to: Distributors and dentists whom have received the concerned product.

Description of the issue:

Certain product lots were labeled with a printed CE mark number that does not apply to the specific product. The correct and applicable CE mark (1250) should have been printed in accordance with relevant requirements in Regulation (EU) 2017/745 (as amended by Regulation (EU) 2023/607).

This labeling oversight is purely administrative in nature and **does not** affect the product's quality, clinical performance, or safety. The affected products remain fully compliant with all intended safety and performance standards, and can be used following its standard instructions for use.

- **Product Safety:** Unchanged — no modifications to design or materials.
- **Product Performance:** Unaffected — clinical effectiveness remains fully ensured.
- **Patient/User Safety:** No increased risk identified.

The following product lots were impacted by this issue:

Lot Number	Expiration Date
CH230251-2025	30-Apr-2026
CH240605	30-Sep-2027
CH240604	30-Sep-2027
CH240606	30-Sep-2027
CH240607	30-Sep-2027
CH240608	30-Sep-2027

Recommended Action for End Users:

No action is required. The affected products can be used according to their standard instructions for use. If you have any questions or concerns regarding this matter, please contact Mr. Christoph Benzinger Head of Quality and Regulatory Affairs via +41 79 455 1546 or christoph.benzinger@vvardis.com

Mr. Christoph Benzinger
Head of Quality and Regulatory Affairs
Zug, Switzerland