Produits Dentaires S.A.
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Vevey, February 17, 2021

DECLARATION

We, **PRODUITS DENTAIRES S.A.**, manufacturer of dental instruments, preparations and medical devices, with factories located in Switzerland, hereby declare that:

Universal Solder

will not be kept as a CE marked medical device under the new Medical Devices Regulation 2017/745 (MDR) as we cannot fully fulfill all the new requirements set by the MDR 2017/745 with this product. Full references and denomination of the product are mentioned next page.

This means that the last production bearing CE mark will take place before the 26th of May 2021 with market distribution until end of stock.

The product will then continue to be manufactured and sold as an industrial solder, with exactly the same specifications and manufacturing process as since 1955 – but without CE marked.

The technical specifications are the following:

Melting Point:	630°C - 700°C.
Composition:	No adverse material in metal composition. Cadmium free.
Mechanical Resistance:	≥ 250 MPa allowing satisfactory resistance as defined by ISO 9333:2006.
Biological tests performed on encapsulated solder:	Non-Cytotoxic - based on XTT Cytotoxicity test on extract according to ISO 10993-5:2009 that was performed on encapsulated solder and was found successful with a percentage of cell viability of 79.5%.
Extraction test performed on encapsulated solder:	Substances present and acceptable - ISO 10993-18 Investigation of inorganic substances after extraction demonstrated that presence of Chromium, Copper, Iron, Nickel, Strontium and Zinc were observable in the samples provided of encapsulated solder. The concentration found were evaluated as acceptable in regard to Permitted Daily Exposures (PDS) or Reference Doses (RfD).

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Despite a heavy work on Technical Documentation and the above-mentioned tests results, compliance with the new General Safety and Performance Requirements from Annex I of the MDR 2017/745 could not be reached without major design rework and change of regulatory strategy.

This led to the decision of stopping the assignment of the Universal Solder as a medical device on the European Market. The PD Universal Solder for industrial purpose used by technicians as raw material for custom made device[1] remains under their own responsibility.

We remain at your disposal if you wish to get further information or technical data.

Produits Dentaires S.A.

Yann Gehrig
CEO

Nicolas Gehrig
President

List of impacted products:

Reference	Name	Packaging	Status
REF 10001	Universal Solder – White	Pack of 12 sticks	Transitioned without CE mark as an industrial solder
REF 10002	Universal Solder – White	Pack of 6 sticks	Transitioned without CE mark as an industrial solder
REF 10011	Universal Solder – White	Pack of 3 sticks	Phase-out
REF 10029	Universal Solder – White	1g	Phase-out
REF 10001mt	Universal Solder – White	Pack of 12 sticks	Phase-out
REF 10002ot	Universal Solder – White	Pack of 6 sticks	Phase-out

[1] Refer to national requirements for possible local restriction or requirements for material to be used for custom made devices.