



EU Declaration of Conformity as per MDR 2017/745

Manufacturer:	PRODUITS DENTAIRES SA Rue des Bosquets 18 1800 Vevey Switzerland
CHRN	CHRN-MF-20000511
SRN	CH-MF-000023147

European Authorized Representative	PD Dental EU Thonon-les-Bains, 74200 France
European Authorized Representative SRN	FR-AR-000017144

We declare under our sole responsibility that the medical device of the following Generic Device Group:

Transparent Strips

Reference:	See attached table
Risk class:	I
As per rule:	5 Annex VIII, MDR 2017/745
Intended Purpose:	Transparent strip for the contouring of restorative materials, mainly light-cured composite for anterior restoration
Trade name:	Transparent Strips ODUS Universal Strips
Basic UDI-DI:	764015916TRANSP_STRIPSQC

Meets all the requirements of the medical device regulation **MDR 2017/745**

Conformity assessment procedure: MDR 2017/745 Article 52, Annex II and III and ODim July 2020.

Quality & Regulatory Affairs Engineer

Silvia Contini

Vevey, 2022-04-22

President

Nicolas Gehrig

Vevey, 2022-04-22



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Transparent Strips

<i>Reference</i>	<i>Designation</i>
42011	TRANSPARENT STRIPS STRAIGHT, 140 x 8 mm, x-thin
42012	TRANSPARENT STRIPS STRAIGHT, 140 x 8 mm, thin
42021	TRANSPARENT STRIPS STRAIGHT, 140 x 10 mm, x-thin
42022	TRANSPARENT STRIPS STRAIGHT, 140 x 10 mm, thin
42211	TRANSPARENT STRIPS CURVED, 70 x 8 mm, x-thin
42212	TRANSPARENT STRIPS CURVED, 70 x 8 mm, thin
42221	TRANSPARENT STRIPS CURVED, 70 x 10 mm, x-thin
42222	TRANSPARENT STRIPS CURVED, 70 x 10 mm, thin
43701d	ODUS UNIVERSAL STRIPS STRAIGHT, 6 mm
43702d	ODUS UNIVERSAL STRIPS STRAIGHT, 8 mm
43703d	ODUS UNIVERSAL STRIPS STRAIGHT, 10 mm
43711d	ODUS UNIVERSAL STRIPS CURVED, 6 mm
43712d	ODUS UNIVERSAL STRIPS CURVED, 8 mm
43713d	ODUS UNIVERSAL STRIPS CURVED, 10 mm