



EU Declaration of Conformity as per MDR 2017/745

Manufacturer:	PRODUITS DENTAIRE 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:

Abrasive Strips

Reference:	See attached table
Risk class:	I
As per rule:	5 Annex VIII, MDR 2017/745
Intended Purpose:	Abrasive strips are used during restorative treatments to adjust / shape / smooth / reduce the interproximal area & contact points of the tooth crown (artificial or natural).
Trade name:	Steel Abrasive Strips Diamond Abrasive Strips
Basic UDI-DI:	++J010ABRASIVESTRIPSW8

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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Abrasive Strips

<i>Reference</i>	<i>Designation</i>
46002	ABRASIVE STRIPS, 2 mm, MEDIUM 1S
46012	ABRASIVE STRIPS, 3 mm, MEDIUM 1S
46021	ABRASIVE STRIPS, 4 mm, FINE 1S
46022	ABRASIVE STRIPS, 4 mm, MEDIUM 1S
46023	ABRASIVE STRIPS, 4 mm, COARSE 1S
46031	ABRASIVE STRIPS, 6 mm, FINE 1S
46032	ABRASIVE STRIPS, 6 mm, MEDIUM 1S
46033	ABRASIVE STRIPS, 6 mm, COARSE 1S
46042	ABRASIVE STRIPS, 8 mm, MEDIUM 1S
46121	ABRASIVE STRIPS, 4 mm, FINE 2S
46122	ABRASIVE STRIPS, 4 mm, MEDIUM 2S
46123	ABRASIVE STRIPS, 4 mm, COARSE 2S
46132	ABRASIVE STRIPS, 6 mm, MEDIUM 2S
46026	ABRASIVE STRIPS, 4mm FINE 1S, Diamond finish, with gap
46027	ABRASIVE STRIPS, 4mm MEDIUM 1S, Diamond finish, with gap
46028	ABRASIVE STRIPS, 4mm MEDIUM 1S, Diamond finish, Perforated, with gap
46051	ABRASIVE STRIPS, 4mm SUPER FINE, 1S, Diamond finish, perforated
46050	ABRASIVE STRIPS, 4mm FINE, 1S, Diamond finish, perforated
46052	ABRASIVE STRIPS, 4mm MEDIUM, 1S, Diamond finish, perforated
46053	ABRASIVE STRIPS, 4mm no grit 1S, with ribbon saw