



EU Declaration of Conformity as per MDR 2017/745

Manufacturer: PRODUITS DENTAIRES SA
Rue des Bosquets 18
1800 Vevey
Switzerland

We declare under our sole responsibility that the medical device:

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 19 and Annex IV

Registered with: Swissmedic
Hallerstrasse 7
3012 Bern
Switzerland

Quality & Regulatory Affairs Director Chloé Fattebert


Vevey, 2021-07-14



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Abrasive Strips

Reference	Designation
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
46050	ABRASIVE STRIPS, 4mm SUPER FINE, 1S, Diamond finish, perforated
46051	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