



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:

Cotton Pellets

Reference: See attached table

Risk class: I

As per rule: 5 Annex VIII, MDR 2017/745

Intended Purpose: Absorbing/drying or applying substances during dental procedure

Basic UDI-DI: 07640159161431

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, 2021-05-21



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Cotton Pellets

<i>Reference</i>	<i>Designation</i>
33251	COTTON PELLETS, N° 1, refill (~3 g)
33252	COTTON PELLETS, N° 2, refill (~3 g)
33253	COTTON PELLETS, N° 3, refill (~3 g)
33254	COTTON PELLETS, N° 4, refill (~3 g)
33255	COTTON PELLETS, N° 5, refill (~3 g)
33261	COTTON PELLETS, N° 1, bulk (32 g)
33262	COTTON PELLETS, N° 2, bulk (32 g)
33263	COTTON PELLETS, N° 3, bulk (18 g)
33264	COTTON PELLETS, N° 4, bulk (18 g)
33265	COTTON PELLETS, N° 5, bulk (18 g)