



## EU Declaration of Conformity as per MDR 2017/745

|               |                                                                          |
|---------------|--------------------------------------------------------------------------|
| Manufacturer: | PRODUITS DENTAIRE SA<br>Rue des Bosquets 18<br>1800 Vevey<br>Switzerland |
| CHRN          | CHRN-MF-20010610                                                         |
| SRN           | CH-MF-000023147                                                          |

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

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

|                       |
|-----------------------|
| <b>Cotton Pellets</b> |
|-----------------------|

|                   |                                                                 |
|-------------------|-----------------------------------------------------------------|
| 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 |
| Trade name:       | Cotton Pellets                                                  |
| Basic UDI-DI:     | 764015916COTTONPELLETS32                                        |
| EMDN:             | Q019004 – DENTAL COTTON ROLLS                                   |

*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.

Regulatory Affairs Specialist /  
Alternate PRRC: Mélissa MOUA

Vevey, 2026-05-26



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### Cotton Pellets

| <b>Reference</b> | <b>Designation</b>                  |
|------------------|-------------------------------------|
| 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) |
| 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)   |
| 33272            | COTTON PELLETS, N° 2, bulk (1 kg)   |