



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:

Matrix Bands and Retainers

Reference: See attached table

Risk class: I

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

Intended Purpose: Anatomically preformed matrix bands used in combination with matrix retainers as part of contouring for restorative treatment. It enables to perform restoration with anatomic proximal contours and contact areas, by creating a temporary interproximal surface (contour).

Trade name: Toffemire Matrix Retainers
Toffemire Matrix Bands
Matrix Bands For Nystroem

Basic UDI-DI: 07640159161448

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, 2021-05-20



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Matrix Bands and Retainers

<i>Reference</i>	<i>Designation</i>
41501	TOFFLEMIRE MATRIX RETAINERS JUNIOR + 12 ass. bands
41502	TOFFLEMIRE MATRIX RETAINERS SENIOR + 12 ass. bands
41503	TOFFLEMIRE MATRIX RETAINERS UNIVERSAL + 12 ass. bands
41504	TOFFLEMIRE MATRIX RETAINERS JUNIOR, alone
41505	TOFFLEMIRE MATRIX RETAINERS SENIOR, alone
41506	TOFFLEMIRE MATRIX RETAINERS UNIVERSAL, alone
41511	TOFFLEMIRE MATRIX BANDS, N° 1, x-thin
41512	TOFFLEMIRE MATRIX BANDS, N° 2, x-thin
41513	TOFFLEMIRE MATRIX BANDS, N° 3, x-thin
41514	TOFFLEMIRE MATRIX BANDS, N° 11, x-thin
41515	TOFFLEMIRE MATRIX BANDS, N° 13, x-thin
41516	TOFFLEMIRE MATRIX BANDS, N° 14, x-thin
41517	TOFFLEMIRE MATRIX BANDS, N° 15, x-thin
41518	TOFFLEMIRE MATRIX BANDS ASSORTED, x-thin
41521	TOFFLEMIRE MATRIX BANDS, N° 1, thin
41522	TOFFLEMIRE MATRIX BANDS, N° 2, thin
41523	TOFFLEMIRE MATRIX BANDS, N° 3, thin
41524	TOFFLEMIRE MATRIX BANDS, N° 11, thin
41525	TOFFLEMIRE MATRIX BANDS, N° 13, thin
41526	TOFFLEMIRE MATRIX BANDS, N° 14, thin
41527	TOFFLEMIRE MATRIX BANDS, N° 15, thin
41528	TOFFLEMIRE MATRIX BANDS ASSORTED, thin
41751	MATRIX BANDS FOR NYSTROEM TYPE 8, N° 6, thin
41752	MATRIX BANDS FOR NYSTROEM TYPE 8, N° 7, thin
41753	MATRIX BANDS FOR NYSTROEM TYPE 8, N° 9, thin
41754	MATRIX BANDS FOR NYSTROEM TYPE 8, N° 10, thin
41755	MATRIX BANDS FOR NYSTROEM TYPE 8, N° 14, thin
41756	MATRIX BANDS FOR NYSTROEM TYPE 8, N° 16, thin
41757	MATRIX BANDS FOR NYSTROEM TYPE 8, ass, N° 6-16, thin
41761	MATRIX BANDS FOR NYSTROEM TYPE 8, N° 6, x-thin
41762	MATRIX BANDS FOR NYSTROEM TYPE 8, N° 7, x-thin
41763	MATRIX BANDS FOR NYSTROEM TYPE 8, N° 9, x-thin
41764	MATRIX BANDS FOR NYSTROEM TYPE 8, N° 10, x-thin
41765	MATRIX BANDS FOR NYSTROEM TYPE 8, N° 14, x-thin
41766	MATRIX BANDS FOR NYSTROEM TYPE 8, N° 16, x-thin
41767	MATRIX BANDS FOR NYSTROEM TYPE 8, ass, N° 6-16, x-thin