



EU Declaration of Conformity as per MDR 2017/745

<i>Manufacturer:</i>	PRODUITS DENTAIRE SA Rue des Bosquets 18 1800 Vevey Switzerland
<i>CHRN</i>	CHRN-MF-20000511
<i>SRN</i>	CH-MF-000023147

<i>European Authorized Representative</i>	PD Dental EU Rue des Arcouasses 4 Thonon-les-Bains, 74200 France
<i>European Authorized Representative SRN</i>	FR-AR-000017144

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

MAP System - Non sterile endodontic material placement instrument MAP Système - Instrument non-stérile pour le placement de matériaux endodontiques
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<i>Reference:</i>	See attached table
<i>Risk class:</i>	Ila
<i>As per rule:</i>	6, Annex VIII, MDR 2017/745
<i>Intended Purpose:</i>	The MAP System is intended for the placement of root canal repair materials.
<i>Trade name:</i>	MAP System
<i>Basic UDI-DI:</i>	764015916MAPSYSTEMYA
<i>EMDN</i>	Q010199 Conservative dentistry and endodontics devices - other
<i>MDN Code</i>	1208 Non-active non-implantable instruments
<i>MDT CODE</i>	MDT 2001 - Devices manufactured using metal processing MDT 2002 - Devices manufactured using plastic processing MDT 2011 - Devices which require packaging, including labelling

*Meets all the requirements of the medical device regulation **MDR 2017/745***



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Conformity assessment procedure: MDR 2017/745 ANNEX IX - Conformity assessment based on a quality management system and on assessment of technical documentation.

Registered with: ICIM SpA (Notified Body 0425)
Piazza Don Enrico Mapelli, 75
20099 Sesto San Giovanni (MI)
Italy

EC certificate number: **0425-MDR-030163-00**

Validity 27.11.2029

Quality & Regulatory Manager Silvia Contini


Vevey, 2025-12-16

References Covered By This Declaration:

Reference	GTIN	Designation
20296	07640159160335	MAP One
20285	07640159160304	MAP Intro Kit
20287	07640159160328	MAP Surgical Kit
20288	07640159163503	MAP VPT Kit

Spare parts		
20200	07640159160106	MAP Plunger, yellow n° 0
20201	07640159160205	MAP Plunger, red N° 1
20202	07640159160212	MAP Plunger, blue N° 2
20203	07640159163534	MAP Plunger VPT N.1 - WHITE
20204	07640159163541	MAP Plunger VPT N.2 - PURPLE
20210	07640159160410	MAP NiTi Memory Shape Needle, Ø 0.85 mm, N°0, yellow



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20211	07640159160427	MAP NiTi Memory Shape Needle, Ø 1.00 mm, N°1, red
20212	07640159160434	MAP NiTi Memory Shape Needle, Ø 1.30 mm, N°2, blue
20220	07640159160359	MAP Classic Needle, Ø 0.90 mm, N°0, yellow
20221	07640159160366	MAP Classic Needle, Ø 1.10 mm, N°1, red
20225	07640159160373	MAP Surgery Needle, right, Ø 0.90 mm, N°0, yellow
20226	07640159160380	MAP Surgery Needle, left, Ø 0.90 mm, N°0, yellow
20227	07640159160397	MAP Surgery Needle, right, Ø 1.10 mm, N°1, red
20228	07640159160403	MAP Surgery Needle, left, Ø 1.10 mm, N°1, red
20263	07640159160052	MAP Hooked Needle, Ø 0.90 mm, N°0, yellow
20264	07640159160076	MAP Hooked Needle, Ø 1.10 mm, N°1, red
20265	07640159160083	MAP Hooked Needle, Ø 1.30 mm, N°2, blue
20218	07640159163510	MAP VPT Needle N.1 - Ø 2.30 mm, WHITE
20219	07640159163527	MAP VPT Needle N.2 - Ø 3.40 mm, PURPLE
20242	07640159160045	MAP Syringe

Accessories related to this device:

20250	07640159160229	MAP Well
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