



Déclaration de Conformité CE
EC Declaration of Conformity

<i>Manufacturer:</i>	PRODUITS DENTAIRES 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 MAP Système

<i>Reference:</i>	<i>See attached table</i>
<i>Risk class:</i>	<i>Ila</i>
<i>As per rule:</i>	6, Annex IX, Directive 93/42/EEC
<i>Intended Purpose:</i>	The MAP System is an endodontic medical device primarily designed for: <ul style="list-style-type: none">• retrograde obturation following apical resection of the root canal,• orthograde obturation of the root canal (pulp capping, perforation, root end filling)
<i>Trade name:</i>	<i>MAP System</i>
<i>Basic UDI-DI:</i>	764015916MAPSYSTEMYA
<i>EMDN</i>	Q010199 Conservative dentistry and endodontics devices - other
<i>MDN Code</i>	MDN 1208 – Non-active non-implantable dental instruments
<i>Conformity assessment procedure:</i>	<i>Directive 93/42/EEC Annex II (excluding section 4) + MDR extension</i> <i>Letter_SGS reference: CLNB1639 – CH/GE 3205871</i>
<i>Registered with:</i>	SGS Belgium NV (Notified Body 1639) SGS House - Noorderlaan 87 2030 Antwerp Belgium

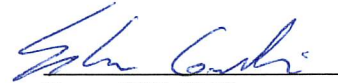


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EC certificate number: CH19/0994

Validity 31.12.2028

Quality & Compliance Manager Silvia Contini


Vevey, 2024-10-29

References Covered By This Declaration:

Reference	GTIN	Designation
20296	07640159160335	"MAP" SYSTEM, MAP One (1 needle-kit)
20285	07640159160304	"MAP" SYSTEM, Intro Kit (3 needle-kit)
20287	07640159160328	"MAP" SYSTEM, Surgical Kit (6 needle-kit)
20200	07640159160106	"MAP" PLASTIC PLUNGER, YELLOW N° 0
20201	07640159160205	"MAP" PLASTIC PLUNGER, RED N° 1
20202	07640159160212	"MAP" PLASTIC PLUNGER, BLUE N° 2
20210	07640159160410	"MAP" "NiTi Memory Shape" NEEDLE, Ø 0.90 mm , N°0 , Yellow (incl. 8 Plastic plungers + 1 cleaning curette)
20211	07640159160427	"MAP" "NiTi Memory Shape" NEEDLE, Ø 1.10 mm , N°1 , red (incl. 8 Plastic plungers + 1 cleaning curette)
20212	07640159160434	"MAP" "NiTi Memory Shape" NEEDLE, Ø 1.30 mm , N°2 , blue (incl. 8 Plastic plungers + 1 cleaning curette)
20220	07640159160359	"MAP" "Classic" NEEDLE, Ø 0.90 mm , N°0 , Yellow (incl. 8 Plastic plungers + 1 cleaning curette)
20221	07640159160366	"MAP" "Classic" NEEDLE, Ø 1.10 mm , N°1 , red (incl. 8 Plastic plungers + 1 cleaning curette)
20225	07640159160373	"MAP" "Surgery" NEEDLE, right, N°0 , Yellow (incl. 8 Plastic plungers + 1 cleaning curette)
20226	07640159160380	"MAP" "Surgery" NEEDLE, left, N°0 , Yellow (incl. 8 Plastic plungers + 1 cleaning curette)
20227	07640159160397	"MAP" "Surgery" NEEDLE, right, N°1 , Red (incl. 8 Plastic plungers + 1 cleaning curette)



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20228	07640159160403	"MAP" "Surgery" NEEDLE, left, N°1 , Red (incl. 8 Plastic plungers + 1 cleaning curette)
20263	07640159160052	"MAP" HOOKED NEEDLE, N°0 YELLOW (incl. 8 Plastic plungers + 1 cleaning curette)
20264	07640159160076	"MAP" HOOKED NEEDLE, N°1 RED (incl. 8 Plastic plungers + 1 cleaning curette)
20265	07640159160083	"MAP" HOOKED NEEDLE, N°2 Blue (incl. 8 Plastic plungers + 1 cleaning curette)
20242	07640159160045	"MAP", STAINLESS STEEL SYRINGE ALONE – Spare part

Accessories related to this device:		
20250	07640159160229	STAINLESS STEEL WELL, pack of 1 piece