



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:

<i>Non-sterile root canal irrigation cannulae</i> <i>Canules non-stériles pour irrigation du canal radiculaire</i>

<i>Reference:</i>	<i>See attached table</i>
<i>Risk class:</i>	<i>Ila</i>
<i>As per rule:</i>	6, Annex VIII, MDR 2017/745
<i>Intended Purpose:</i>	Needle / Cannula intended for root canal irrigation during endodontic procedure for the treatment of dental infection and traumatic dental injury
<i>Trade name:</i>	<i>IrriFlex</i> <i>Irrigation Needle</i> <i>Eddy Flex. Cannula</i> <i>TruAnatomy</i>
<i>Basic UDI-DI:</i>	764015916CANNULASXW
<i>EMDN</i>	Q010599 Dental Instruments, single use - other
<i>MDN Code</i>	1208 Non-active non-implantable instruments

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

<i>Conformity assessment procedure:</i>	<i>MDR 2017/745 ANNEX IX - Conformity assessment based on a quality management system and on assessment of technical documentation.</i>
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Registered with: SGS Belgium NV (Notified Body 1639)
SGS House - Noorderlaan 87
2030 Antwerp
Belgium

EC certificate number: **CH24/00000115**

Validity 28.11.2029

Quality & Compliance Manager Silvia Contini


Vevey, 2024-12-05

References Covered By This Declaration:

Reference	Designation
21400	IrriFlex, x20
21401	IrriFlex, x40
21401xxx	Irriflex for distribution*
21403	IrriFlex, x5
BNSTNIRD2230G	TRUNATOMY Irrigation Needle 30G x40 Product Distributed by Maillefer Instruments Holding
TRNIN30G40	TRUNATOMY Irrigation Needle 30G x40 Product Distributed by Tulsa Dental Specialties
MNSEDIRD2230G	EDDY Flex.Cannula Irrigation Needle x40 Product Distributed by VDW
BNSDSIN12230G	Irrigation Needle 30G x1 Product Distributed by Maillefer Instruments Holding
BNSDSIN52230G	Irrigation Needle 30G x5 Product Distributed by Maillefer Instruments Holding
BNSDSIND2230G	Irrigation Needle 30G x40 Product Distributed by Maillefer Instruments Holding
DSIN30G1	Irrigation Needle 30G x1 Product Distributed by Dentsply Tulsa Dental Specialties
DSIN30G5	Irrigation Needle 30G x5 Product Distributed by Dentsply Tulsa Dental Specialties
DSIN30G40	Irrigation Needle 30G x40 Product Distributed by Dentsply Tulsa Dental Specialties

*The only difference between the references 21401 and 21401xxx is in the packaging layout, which is personalized with the distributor's information. "xxx" are three letters indicating the distributor.