



**Déclaration de Conformité CE**  
**EC Declaration of Conformity**

Fabricant : PRODUITS DENTAIRES SA  
Manufacturer : 18, Rue des Bosquets  
1800 Vevey  
Switzerland (CH)

Nous déclarons sous notre propre responsabilité que le dispositif médical :  
*We declare under our sole responsibility that the medical device:*

**Canules non-stériles pour irrigation du canal radicaire**  
***Non-sterile root canal irrigation cannulae***

Référence : Voir tableau annexé  
*Reference : See attached table*

De classe :  
*Of class :* IIa

Selon la règle :  
*As per rule:* 6

Remplit toutes les exigences applicables de la Directive sur les Dispositifs Médicaux 93/42/CEE comme amendée par la directive 2007/47/CEE.

*Fulfills all applicable requirements of the Medical Device Directive 93/42/EEC as amended by directive 2007/47/EEC.*

Procédure d'évaluation de la conformité : Directive 93/42/CEE Annexe II (à l'exclusion de la section 4)  
*Conformity assessment procedure: Directive 93/42/EEC Annex II (excluding section 4)*

Enregistré auprès de : SGS Belgium NV (Notified Body 1639)  
*Registered with : SGS House - Noorderlaan 87*  
2030 Antwerp  
Belgium

Numéro du certificat CE : CH19/0994  
*EC certificate number :*

Quality & Regulatory Director

Chloé Fattebert



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**Canules non-stériles pour irrigation du canal radiculaire**  
***Non-sterile root canal irrigation cannulae***

Table des Références  
*References table*

Le tableau suivant répertorie les références concernées par le présent certificat  
*The following table lists the items covered by this certificate*

<b>Référence</b> <i>Reference</i>	<b>Désignation</b> <i>Designation</i>
21400	IRRIFLEX, box of 20 cannulas
21401	IRRIFLEX, box of 40 cannulas
<b>BNSTNIRD2230G</b>	<b>TRUNATOMY Irrigation Needle 30G x40</b> Product Distributed by Maillefer Instruments Holding
<b>MNSEDIRD2230G</b>	<b>EDDY Flex.Cannula Irrigation Needle</b> Product Distributed by VDW
<b>TRNIN30G40</b>	<b>TRUNATOMY Irrigation Needle 30G x40</b> Product Distributed by Dentsply Tulsa Dental Specialties
<b>BNSDSIN12230G</b>	<b>Irrigation Needle 30G x1</b> Product Distributed by Maillefer Instruments Holding
<b>BNSDSIN52230G</b>	<b>Irrigation Needle 30G x5</b> Product Distributed by Maillefer Instruments Holding
<b>BNSDSIND2230G</b>	<b>Irrigation Needle 30G x40</b> Product Distributed by Maillefer Instruments Holding
<b>DSIN30G1</b>	<b>Irrigation Needle 30G x1</b> Product Distributed by Dentsply Tulsa Dental Specialties
<b>DSIN30G5</b>	<b>Irrigation Needle 30G x5</b> Product Distributed by Dentsply Tulsa Dental Specialties
<b>DSIN30G40</b>	<b>Irrigation Needle 30G x40</b> Product Distributed by Dentsply Tulsa Dental Specialties