



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

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

Mandataire Européen :  
*European Authorized Representative :* PD Dental EU  
Thonon-les-Bains, 74200  
France

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 radiculaire**  
***Non-sterile root canal irrigation cannulae***

Référence :  
*Reference :* Voir tableau annexé  
*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 :  
*Conformity assessment procedure:* Directive 93/42/CEE Annexe II (à l'exclusion de la section 4)  
*Directive 93/42/EEC Annex II (excluding section 4)*

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

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

Quality & Regulatory Director  
Chloé Fattebert



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

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