



Déclaration de Conformité CE
EC Declaration of Conformity

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

Mandataire Européen : PD Dental EU
European Authorized Representative : 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 : 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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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

Référence <i>Reference</i>	Désignation <i>Designation</i>
21400	IRRIFLEX, box of 20 canulas
21401	IRRIFLEX, box of 40 canulas
BNSTNIRD2230G	TRUNATOMY Irrigation Needle 30G x40 Product Distributed by Maillefer Instruments Holding
MNSEDIRD2230G	EDDY Flex.Cannula Irrigation Needle Product Distributed by VDW
TRNIN30G40	TRUNATOMY Irrigation Needle 30G x40 Product Distributed by Dentsply Tulsa Dental Specialties
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