EC Certificate Full Quality Assurance System: CH12/0484

The management system of

Produits Dentaires SA

18 rue des Bosquets, Vevey, 1800, Switzerland

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 18 November 2015 until 08 June 2020
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 08 June 2018
Issue 2. Certified since 10 June 2012

Certification is based on reports numbered CH/GE 3302657

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
SGS United Kingdom Ltd Systems & Services Certification
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 **f** +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M2

Produits Dentaires SA

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 2

Detailed scope

Non-sterile drills, reamers and burs for dental application, non-sterile polishers, non-sterile endodontic material placement instruments, non-sterile zinc oxide based dental filling materials, non-sterile mineral based dental filling materials, non-sterile gutta-percha stopping and points, non-sterile dental varnish, non-sterile calcium hydroxide based dental filling materials, non-sterile composite based restorative materials, non-sterile dental desobturating materials, non-sterile endodontic cleaning and irrigation materials, non-sterile dental posts, sterile and non-sterile paper points, non-sterile obturation points, non-sterile paste fillers, non-sterile glass ionomer based dental filling materials.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market