EC Certificate Full Quality Assurance System: Certificate CH12/1200

The management system of

FKG Dentaire SA

Crêt-du-Locle 4,
CH - 2304 La Chaux-de-Fonds

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

Sterile and non-sterile alternative and rotative instruments and sterile hand tools for root canal preparation during endodontic treatment
Sterile and non-sterile rotative instruments and sterile hand tools for canal obturation preparation during endodontic treatment
Non-sterile materials for dental reconstruction

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.

This certificate is valid from 20 February 2019 until 5 November 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 5 November 2019
Issue 14. Certified since 27 July 1998

Certification is based on reports numbered CH/GE 3301350

Authorised by

Jonathan M. Hall

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

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