EC Certificate Full Quality Assurance System: Certificate CH19/0967

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

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 16 December 2019 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 27 July 1998
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered CH/GE 3301350

Authorised by

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