



Certificate Number CH19/1052

The quality management system of

FKG Dentaire SA

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

Dun & Bradstreet D-U-N-S identification number: 48-288-4061

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate

MDSAP(ISO 13485:2016)

Australia:

Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure [including design]

Brazil:

RDC ANVISA n. 16/2013 / RDC ANVISA n. 23/2012 / RDC ANVISA n. 67/2009

Canada:

Medical Devices Regulations – Part 1 SOR 98/282

Japan:

MHLW Ministerial Ordinance 169, Article 4 to Article 68 / PMD Act

United States:

21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D



For the following activities and devices

Design, development, manufacturing and distribution of instruments and materials for endodontics and dental reconstruction.

This certificate is valid from

Effective Date: 2019-12-17 until Expiry Date: 2021-12-16 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 2022-11-05

Issue 1. Certified since 2019-12-17

Authorised by J Hall
Business Manager

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SGS MDSAP 1116

Page 1 of 1



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