Certificate CH19/1052

The quality management system of

FKG Dentaire Sàrl

Le Crêt-du-Locle 4, CH - 2322 Le Crêt-du-Locle

Facility number : F003524

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

Australia: Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 - Full Quality Assurance System; Therapeutic Goods (Medical Devices) Regulations 2002,
Brazil: RDC ANVISA n. 665/2022; RDC ANVISA n. 551/2021; RDC ANVISA n. 67/2009
Canada: Medical Devices Regulations – Part 1 SOR 98/282
Japan: MHLW Ministerial Ordinance No.169 (2004) as amended by MHLW Ordinance No. 128 (2014) Articles 4 to 68; PMD Act
United States: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing; 21 CFR Part 820 - Quality System Regulation

For the following activities

Design, Development, manufacturing and distribution, of sterile and non-sterile instruments and materials for endodontics and dental reconstruction.

This certificate is valid from Effective date 2022-11-29 until Expiry date 2025-11-05 November and remains valid subject to satisfactory surveillance

Issue 4. Certified since 2019-12-17

Authorised by
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Head of Notified Body 1639

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