

The management system of  
**FKG Dentaire SA**

Crêt-du-Loche 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**

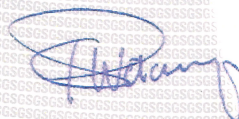
Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

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



**SGS Belgium NV, Notified Body 1639**

SGS House Noorderlaan 87 2030 Antwerp Belgium  
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LPMD5007 - Certificate CE1639 Annex II-4, EN rev. 02

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# FKG Dentaire SA

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

**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**

This corrigendum is only valid together with accompanying 93/42/EEC certificate  
Issue 1

<b>Correction Date</b>	<b>Correction</b>
Change approved by SGS on 26 August 2021	Name Change from FKG Dentaire SA to FKG Dentaire Sàrl
	Change address from Crêt-du-Loche 4 to Le Crêt-du-Loche 4
	Change postal code and location from 2304 La Chaux-de-Fonds to 2322 Le Crêt-du-Loche
	Add secondary address Le Crêt-du-Loche 4, Case Postale, 2301 La Chaux- de-Fonds

Authorised by

Global Medical Devices Certification Manager

## SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium  
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SGS Belgium NV

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