

EC Certificate Production Quality Assurance System: Certificate KR19/81826279

The management system of

C-K DENTAL IND. CO., LTD.

88-50, Sudo-ro, Bucheon-si, Gyeonggi-do, Republic of Korea

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

Sterile single use dental needles: Sterile single use endodontic irrigation needles

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination

Certificate according to Annex III 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 13 March 2023 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 13 February 2018 and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered WW/PCI/ 211452

Authorised by

SGS Belgium NV, Notified Body 1639

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