EU Quality Management System Certificate KR24/00000049

The management system of

C-K DENTAL IND. CO., LTD.

88-50, Sudo-ro, Bucheon-si, Gyeonggi-do, 14519, Republic of Korea

SRN Number: KR-MF-000022929

has been assessed and certified as meeting the requirements of

MDR EU Quality Management System certificate (Annex IX QMS)

For the following products

The Scope of Registration appears on page 2 of this certificate

This certificate is valid from 24 June 2024 until 24 June 2029 and remains valid subject to satisfactory surveillance audits.
Recertification audit due before 24 December 2028
Issue 1. Certified since 24 June 2024

Authorised by
Virginie Siloret
Global Medical Device
Certification Manager
SGS Belgium NV NB1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
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C-K DENTAL IND. CO., LTD.

MDR EU Quality Management System certificate (Annex IX QMS)

Class IIa Devices

MDN1202, MDS1005

Sterile single use dental needles
[Basic UDI-DI: 88000445DN25314T]

Sterile single use endodontic irrigation needles
[Basic UDI-DI: 88000445ED1631ZM]

Conditions for & limitation to the validity of the certificate:
For placing on the market of Class III or class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors and Annex VIII rule 12 devices) covered by this certificate, a Technical Documentation Assessment Certificate according to Annex IX section 4 and 5 is required.

For Class I devices, audit done by SGS Belgium N.V. is limited to the specific aspect described in Article 52 section 7 of MDR (EU) 2017/745 (sterility, reusability or measurement function).

List of examinations and tests performed, which may include reference to relevant CS and harmonised standards, as per Annex XII, Chapter II, section 10 is available “on request" per email to NB1639@sgs.com.

Certification is based on following reports: - WW/PCI/211452 - S2A 10.1 + TFR 10.2
Authorized representative name and address (if relevant): OBELIS S.A, Bd. Général Wahis 53, 1030 Brussels, Belgium
Previous certificate number: N/A
Change in between this certificate and previous one: N/A