

EC Declaration of Conformity

Manufacturer name and address: C-K DENTAL IND.CO.,LTD.
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SRN (Single Registration Number): KR-MF-000022929

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Bd. Général Wahis 53, 1030 Brussels, Belgium
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Name of the Device(s): Sterile single use dental needles
Commercial/Trade name: Annex – List of Devices Covered by the Declaration of Conformity
Basic UDI-DI: 88000445DN25314T
GMDN Code and Term: 12740/ Dental syringe needles, single-use
EMDN Code and Term: A010601/ CARPULE NEEDLES

We, C-K DENTAL IND.CO.,LTD. hereby declare under our sole responsibility that the device(s) listed in the attached Annex comply with the provisions of the REGULATION (EU) 2017/745.

The device(s) is/are Class IIa following Rule 6 of Annex VIII of REGULATION (EU) 2017/745.

The conformity assessment procedure has been performed following Annex IX (Quality Management System & technical documentation) of Art 52 (6) and the following CE certificate KR24/00000049 has been issued by SGS Belgium NV, Notified Body 1639.

This declaration is supported by the Quality Management System Certificate KR05/63877 to EN ISO 13485:2016 issued by SGS United Kingdom Ltd.

The present declaration is in conformity with the Regulation (EU) 2017/745 and following standards:
ISO 7885:2010, ISO 9626:2016, EN ISO 13485:2016, EN ISO 14971:2019, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-7:2008/Amd.1:2019, ISO 10993-10:2021, ISO 10993-11:2017, EN ISO 10993-23:2021, ISO 11135:2014, ISO 11607-1/2:2019, EN ISO 11737-1:2018(ISO 11737-1:2018), EN ISO 11737-2:2020(ISO 11737-2:2019), ISO 14644-1:2015, EN ISO 15223-1:2021.

C-K DENTAL IND.CO.,LTD.
88-50, Sudo-ro, Bucheon-si,
Gyeonggi-do, Republic of Korea

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Issue place and date (24-06-24/R2)



Signature :

A handwritten signature in black ink, appearing to read 'SI NAE, KANG'.

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Name : SI NAE, KANG

Position : PRRC

Annex – List of Devices Covered by the Declaration of Conformity

No.	Brand name	Product code	Size and Threaded type	UDI-DI
1	C-K JECT	27-21-M	27G X 21mm (0.4 X 21mm), Metric	08800044506344
		27-23-M	27G X 23mm (0.4 X 23mm), Metric	08800044506351
		27-25-M	27G X 25mm (0.4 X 25mm), Metric	08800044506368
		27-30-M	27G X 30mm (0.4 X 30mm), Metric	08800044506375
		27-32-M	27G X 32mm (0.4 X 32mm), Metric	08800044506382
		27-35-M	27G X 35mm (0.4 X 35mm), Metric	08800044506399
		27-38-M	27G X 38mm (0.4 X 38mm), Metric	08800044506405
		27-40-M	27G X 40mm (0.4 X 40mm), Metric	08800044506412
		30-12-M	30G X 12mm (0.3 X 12mm), Metric	08800044506429
		30-14-M	30G X 14mm (0.3 X 14mm), Metric	08800044506436
		30-15-M	30G X 15mm (0.3 X 15mm), Metric	08800044506443
		30-16-M	30G X 16mm (0.3 X 16mm), Metric	08800044506450
		30-18-M	30G X 18mm (0.3 X 18mm), Metric	08800044506467
		30-21-M	30G X 21mm (0.3 X 21mm), Metric	08800044506474
		30-23-M	30G X 23mm (0.3 X 23mm), Metric	08800044506481
		30-25-M	30G X 25mm (0.3 X 25mm), Metric	08800044506498
		30-30-M	30G X 30mm (0.3 X 30mm), Metric	08800044506504
		31-12-M	31G X 12mm (0.25 X 12mm), Metric	08800044506528
		31-14-M	31G X 14mm (0.25 X 14mm), Metric	08800044506535
		31-15-M	31G X 15mm (0.25 X 15mm), Metric	08800044506542
		31-16-M	31G X 16mm (0.25 X 16mm), Metric	08800044506559
		31-18-M	31G X 18mm (0.25 X 18mm), Metric	08800044506566
		27-21-I	27G X 21mm (0.4 X 21mm), Inch	08800044500007
		27-23-I	27G X 23mm (0.4 X 23mm), Inch	08800044500014
		27-25-I	27G X 25mm (0.4 X 25mm), Inch	08800044500021
		27-30-I	27G X 30mm (0.4 X 30mm), Inch	08800044500038
		27-32-I	27G X 32mm (0.4 X 32mm), Inch	08800044500045
		27-35-I	27G X 35mm (0.4 X 35mm), Inch	08800044500052
		27-38-I	27G X 38mm (0.4 X 38mm), Inch	08800044500069
		27-40-I	27G X 40mm (0.4 X 40mm), Inch	08800044500076
		30-12-I	30G X 12mm (0.3 X 12mm), Inch	08800044500083
		30-14-I	30G X 14mm (0.3 X 14mm), Inch	08800044500090
		30-15-I	30G X 15mm (0.3 X 15mm), Inch	08800044500106

		30-16-I	30G X 16mm (0.3 X 16mm), Inch	08800044500113
		30-18-I	30G X 18mm (0.3 X 18mm), Inch	08800044500120
		30-21-I	30G X 21mm (0.3 X 21mm), Inch	08800044500137
		30-23-I	30G X 23mm (0.3 X 23mm), Inch	08800044500144
		30-25-I	30G X 25mm (0.3 X 25mm), Inch	08800044500151
		30-30-I	30G X 30mm (0.3 X 30mm), Inch	08800044500168
		31-12-I	31G X 12mm (0.25 X 12mm), Inch	08800044500182
		31-14-I	31G X 14mm (0.25 X 14mm), Inch	08800044500199
		31-15-I	31G X 15mm (0.25 X 15mm), Inch	08800044500205
		31-16-I	31G X 16mm (0.25 X 16mm), Inch	08800044500212
		31-18-I	31G X 18mm (0.25 X 18mm), Inch	08800044500229