

EC Declaration of Conformity

DATE: MAY 01, 2020 Rev. 08

C-K DENTAL IND.CO.,LTD.

88-50, Sudo-Ro, Bucheon-Si, Gyeonggi-Do, Republic of Korea

Declaration that **STERILE SINGLE USE DENTAL NEEDLES** are in conformity with the Essential Requirements for the COUNCIL DIRECTIVE 93/42/EEC amended by DIRECTIVE 07/47/EC concerning medical device.

The devices have been classified as 'Class IIa' in accordance with Annex IX, Rule 6 of MDD 93/42/EEC amended by MDD/07/47/EC

☞ **HARMONIZED STANDARDS:** ISO 7885, ISO 9626, ISO 7864, ISO 10993-1

☞ **GENERIC DEVICE TERM:** STERILE SINGLE USE DENTAL NEEDLES

☞ **COMMERCIAL NAME:** C-K JECT

☞ **MODEL SIZE:** 25GX21mm, 25GX23mm, 25GX25mm, 25GX30mm, 25GX32mm, 25GX35mm, 25GX38mm, 25GX40mm, 27GX21mm, 27GX23mm, 27GX25mm, 27GX30mm, 27GX32mm, 27GX35mm, 27GX38mm, 27GX40mm, 30GX12mm, 30GX14mm, 30GX15mm, 30GX16mm, 30GX18mm, 30GX21mm, 30GX23mm, 30GX25mm, 30GX30mm, 31GX8mm, 31GX12mm, 31GX14mm, 31GX15mm, 31GX16mm, 31GX18mm

☞ **GMDN CODE:** 12740

☞ **GMDN TERM:** Dental syringe needles, single-use

☞ **EC CERTIFICATE NUMBER:** KR19/81826279

The procedure set out in Annex V of Directive 93/42/EEC amended by MDD/07/47/EC has been applied in order to affix the CE marking to this device under the supervision of SGS Belgium NV, Notified Body 1639.

☞ **EC REPRESENTATIVE:** Obelis s.a.

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Bong Yik Cho

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