

EC Certificate Full Quality Assurance System: Certificate KR19/81826339

The management system of

GS Medical Co., Ltd.

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Cheongju-si, Chungcheongbuk-do, 28161, Korea

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

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 27 July 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.

Issue 3. Certified since 21 January 2005
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered WW/PCI 211154

Authorised by

SGS Belgium NV, Notified Body 1639

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GS Medical Co., Ltd.

Directive 93/42/EEC on medical devices, Annex II (excluding section 4)

Issue 3

Detailed scope

Non sterile spinal fixation system (GSS Pedicle Screw System, CEDAR Pedicle Screw System, SKY Reconstruction system, AnyPlus Pedicle Screw System, AnyPlus Cervical Plate System);

Sterile and non sterile Lumbar PEEK Cage system (AnyPlus PEEK Cage System) and non sterile Cervical PEEK Cage system (AnyPlus PEEK Cage System);

Sterile single use inflatable bone expander system (Tracker-X, Tracker-P);

Sterile single use cement dispenser system (Tracker-I);

Sterile single use epidural catheter system (Abel Epidural Catheter System, EPISOL Epidural Catheter System)

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