EC Certificate Full Quality Assurance System: Certificate KR19/81826231

The management system of

SPIDENT Co., Ltd.

203 & 312, Korea Industrial Complex, 722, Gojan-Dong,
Namdong-Gu Incheon, 405-821, 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 16 December 2019 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 29 November 1999
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered WW/PCI 200712

Authorised by

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SPIDENT Co., Ltd.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 1

Detailed scope

Gutta Percha Points ;

Sterile Absorbent Paper Points ;

Dental etchant ;

Dental light-cured temporary filling material ;

Dental light-cured pit and fissure sealant ;

Dental light-cured flowable resin ;

Dental light-cured base and liner ;

Dental temporary cement ;

Dental light-cured composite resin ;

Dental light-cured bonding agent ;

Core build up resin ;

Dental temporary resin cement ;

Dental light-cured bonding activator;

Sterile single use dental needles;

Root canal sealing & filling material;

Temporary root canal filling material;

Radiopaque glass ionomer filling material

Self-adhesive resin cement

Temporary crown & bridge resin

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