

EC Certificate Full Quality Assurance System: KR99/51093

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 30 July 2019 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 18 May 2022

Issue 20. Certified since 29 November 1999

Certification is based on reports numbered WW/PCI 200712

Authorised by

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EC Certificate Full Quality Assurance System:
Certificate KR99/51093, continued

SPIDENT Co., Ltd.

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

Issue 20

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