# 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**

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