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

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

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

Manufacturer's Self-Declaration

in relation to Regulation 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to:

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service
-

Manufacturer name	SPIDENT CO., LTD.
Manufacturer address and contact details	109, 117, 203, 304, 307, 312, 314, 315 & 316, Korea Industrial Complex, 722, Gojan-Dong, Namdong-Gu, Incheon, 405-821, Republic of Korea
Single Registration Number (SRN) (if available)	KR-MF-000008691

Authorised Representative name (if applicable)	AR Experts B.V
Authorised Representative address and contact details	Amerlandseweg 7, 3621 ZC, Breukelen, the Netherlands
Single Registration Number (SRN) (if available)	NL-AR-000023989

Notified body name (if applicable)	SGS Belgium NV □ See attached schedule
Notified body number (if applicable)	1639 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	KR19/81826231 □ See attached schedule
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	□ See attached schedule

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Manufacturer's Self-Declaration

End date of extended validity/transition period	□ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*

  ☐ Expired *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

Manufacturer's Self-Declaration

- ■ Expired/expires *after* 20 March 2023:
  - ■ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
  - ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

Manufacturer's Self-Declaration

➢ **Up-classified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

- *Choose one applicable statement:*

☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

■ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Manufacturer's Self-Declaration

Signed for and on behalf of the manufacturer:

Full Company Name : SPIDENT Co., Ltd.

Location & Date : SPIDENT Co., Ltd & January 5, 2024

Signature, Print Name, Title

Tae-Hoon Kim, PRRC

Manufacturer's Self-Declaration

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**If the MDR device is a substitute device, identification of the corresponding MDD device**	**MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
Dental Etchant (FineEtch, Etch 37%, ToDent Etsgel, Ocean, Gel Demineralizant, Dento-Etch) /880926295FEZQ	Rule 6 , Class IIa	NA	KR19/81826231 SGS Belgium NV, Notified Body 1639	2024.05.24	31 December 2028
Dental light-cured flowable resin (EsFlow, Flow, ToDent Flow, Elegance Flow) /880926295FI23	Rule 19 , Class IIa	NA	KR19/81826231 SGS Belgium NV, Notified Body 1639	2024.05.24	31 December 2028
Sterile single use dental needles (SPIDENT NOP, Dental Needles, Sterile Single Use Dental Needles, BlueTech) /880926295NOPUG	Rule 6 , Class IIa	NA	KR19/81826231 SGS Belgium NV, Notified Body 1639	2024.05.24	31 December 2028
Dental light-cured temporary filling material (Temp·it, OBTURACIÓN TEMPORAL INLAY/ONLAY(UNIVERSAL), Medicaline mBasic) /880926295TB2X	Rule 19 , Class IIa	NA	KR19/81826231 SGS Belgium NV, Notified Body 1639	2024.05.24	31 December 2028
Dental light-cured composite resin	Rule 19 , Class IIa	NA	KR19/81826231	2024.05.24	31 December 2028

Manufacturer's Self-Declaration

(EsCom100, Nanofill+, Nanohybrid Composite+) /880926295EFZP			SGS Belgium NV, Notified Body 1639		
Self-Adhesive Resin Cement (EsCem, mZem Plus) /880926295ESCSM	Rule 19 , Class IIa	NA	KR19/81826231 SGS Belgium NV, Notified Body 1639	2024.05.24	31 December 2028
Dental light-cured bonding agent (EsBond, ToDent Bond LC, Nexus, NanoBond) /880926295EBZF	Rule 8 , Class IIa	NA	KR19/81826231 SGS Belgium NV, Notified Body 1639	2024.05.24	31 December 2028
Dental Temporary Cement (EsTemp NE, ToDent Temp NE, mZem Tempo) /880926295ET2N	Rule 7 , Class IIa	NA	KR19/81826231 SGS Belgium NV, Notified Body 1639	2024.05.24	31 December 2028
Dental light-cured temporary filling material (Temp·it Flow) /880926295TF37	Rule 19 , Class IIa	NA	KR19/81826231 SGS Belgium NV, Notified Body 1639	2024.05.24	31 December 2028
Dental temporary resin cement (EsTemp Implant, EsTemp Clear) /880926295EIZV	Rule 19 , Class IIa	NA	KR19/81826231 SGS Belgium NV, Notified Body 1639	2024.05.24	31 December 2028
Temporary root canal filling material (VioPaste, HIDRÓ XIDO DE CALCIO CON SULFATO DE BARIO EN BASE DE AGUA, UnoCal NS) /880926295VA33	Rule 7 , Class IIa	NA	KR19/81826231 SGS Belgium NV, Notified Body 1639	2024.05.24	31 December 2028
Root canal sealing & filling material (VioSeal, SELLADOR DE CANALES, UnoSeal R) /880926295VS47	Rule 8 , Class IIa	NA	KR19/81826231 SGS Belgium NV, Notified Body 1639	2024.05.24	31 December 2028

Manufacturer's Self-Declaration

Dental light-cured base and liner (Base•it, Base, ToDent Base LC) /880926295BIZL	Rule 19 , Class IIa	NA	KR19/81826231 SGS Belgium NV, Notified Body 1639	2024.05.24	31 December 2028
Core build up resin (Core•it Dual, ToDent Core Dual, RECONSTRUCTOR DE MUÑ ONES, Kentcore, Supracore) /880926295CBZ9	Rule 19 , Class IIa	NA	KR19/81826231 SGS Belgium NV, Notified Body 1639	2024.05.24	31 December 2028
Dental light-cured pit and fissure sealant (Seal•it, Seal, ToDent Seal LC, SELLADOR DE PUNTOS Y FISURAS) /880926295SI3A	Rule 19 , Class IIa	NA	KR19/81826231 SGS Belgium NV, Notified Body 1639	2024.05.24	31 December 2028

Notified Body Confirmation Letter Reference: C676129

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

SPIDENT CO., LTD.
109, 117, 203, 304, 307, 312, 314, 315 & 316,
Korea Industrial Complex, 722, Gojan-Dong,
Namdong-Gu, Incheon, 405-821, Republic of Korea

SRN Number: KR-MF-000008691

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

Place and date:
Høvik, 16.08.2024

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Menaka Singh
Management Representative

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Dental Etchant (FineEtch, Etch 37%, ToDent Etsgel, Ocean, Gel Demineralizant, Dento-Etch) /880926295FEZQ	Class IIa	N/A	Certificate number: KR19/81826231 NB number: 1639 (SGS Belgium NV) Expiry date : 24 May 2024
Dental light-cured flowable resin (EsFlow, Flow, ToDent Flow, Elegance Flow) /880926295FI23	Class IIa	N/A	Certificate number: KR19/81826231 NB number: 1639 (SGS Belgium NV) Expiry date : 24 May 2024
Sterile single use dental needles (SPIDENT NOP, Dental Needles, Sterile Single Use Dental Needles, BlueTech) /880926295NOPUG	Class IIa	N/A	Certificate number: KR19/81826231 NB number: 1639 (SGS Belgium NV) Expiry date : 24 May 2024
Dental light-cured temporary filling material (Temp·it, OBTURACIÓN TEMPORAL INLAY/ONLAY(UNIVERSAL), Medicaline mBasic) /880926295TB2X	Class IIa	N/A	Certificate number: KR19/81826231 NB number: 1639 (SGS Belgium NV) Expiry date : 24 May 2024
Dental light-cured composite resin (EsCom100, Nanofill+, Nanohybrid Composite+) /880926295EFZP	Class IIa	N/A	Certificate number: KR19/81826231 NB number: 1639 (SGS Belgium NV) Expiry date : 24 May 2024

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Self-Adhesive Resin Cement (EsCem, mZem Plus) /880926295ESCSM	Class IIa	N/A	Certificate number: KR19/81826231 NB number: 1639 (SGS Belgium NV) Expiry date : 24 May 2024
Dental light-cured bonding agent (EsBond, ToDent Bond LC, Nexus, NanoBond) /880926295EBZF	Class IIa	N/A	Certificate number: KR19/81826231 NB number: 1639 (SGS Belgium NV) Expiry date : 24 May 2024
Dental Temporary Cement (EsTemp NE, ToDent Temp NE, mZem Tempo) /880926295ET2N	Class IIa	N/A	Certificate number: KR19/81826231 NB number: 1639 (SGS Belgium NV) Expiry date : 24 May 2024
Dental light-cured temporary filling material (Temp·it Flow) /880926295TF37	Class IIa	N/A	Certificate number: KR19/81826231 NB number: 1639 (SGS Belgium NV) Expiry date : 24 May 2024
Dental temporary resin cement (EsTemp Implant, EsTemp Clear) /880926295EIZV	Class IIa	N/A	Certificate number: KR19/81826231 NB number: 1639 (SGS Belgium NV) Expiry date : 24 May 2024
Temporary root canal filling material (VioPaste, HIDRÓ XIDO DE CALCIO CON SULFATO DE BARIO EN BASE DE AGUA, UnoCal NS) /880926295VA33	Class IIa	N/A	Certificate number: KR19/81826231 NB number: 1639 (SGS Belgium NV) Expiry date : 24 May 2024
Root canal sealing & filling material VioSeal, SELLADOR DE CANALES, UnoSeal R) /880926295VS47	Class IIa	N/A	Certificate number: KR19/81826231 NB number: 1639 (SGS Belgium NV) Expiry date : 24 May 2024
Dental light-cured base and liner (Base•it, Base, ToDent Base LC) /880926295BIZL	Class IIa	N/A	Certificate number: KR19/81826231 NB number: 1639 (SGS Belgium NV) Expiry date : 24 May 2024
Core build up resin	Class IIa	N/A	Certificate number:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
(Core•it Dual, ToDent Core Dual, RECONSTRUCTOR DE MUÑ ONES, Kentcore, Supracore) /880926295CBZ9			KR19/81826231 NB number: 1639 (SGS Belgium NV) Expiry date : 24 May 2024
Dental light-cured pit and fissure sealant (Seal•it, Seal, ToDent Seal LC, SELLADOR DE PUNTOS Y FISURAS) /880926295SI3A	Class IIa	N/A	Certificate number: KR19/81826231 NB number: 1639 (SGS Belgium NV) Expiry date : 24 May 2024

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
NA	NA	NA	NA

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/08/16	C676129	Initial issue

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607.
- Significant changes to design or intended purpose of the devices.
- Changes in the quality system affecting production.
- Periodical audits not held within the timeframe.