



EC Declaration of Conformity

Manufacturer: SPIDENT CO., LTD.

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European representative: AR EXPERTS B.V. (tradenname: CE Medical)
Amerlandseweg 7, 3621 ZC, Breukelen, the Netherlands
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Product: EsFlow, EsFlow Standing Kit, Dental light-cured flowable resin

Classification: Class IIa by Rule 8 of Annex IX, MDD 93/42/EEC as amended by 2007/47/EC

GMDN Code: 35870, Dental composite resin

Conformity Assessment Route: Annex II, Excluding Section 4, MDD 93/42/EEC as amended by 2007/47/EC

Notified Body: SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium

Applied reference: ISO 13485, ISO 14971, ISO 15223-1, ISO 4049

EC certificate: KR19/81826231

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Start of CE-marking: November, 2005

Place, Date of issue: Incheon, Korea, May 24, 2024

Date of validity: December 31, 2028

SPIDENT CO., LTD.

Signature: _____

JeMo Ahn/President
On behalf of SPIDENT Co., Ltd.