EC Declaration of Conformity

Manufacturer:	SPIDENT CO., LTD.
Address:	203 & 312, Korea Industrial Complex, 722, Gojan-Dong, Namdong-Gu, Incheon, Korea 405-821 TEL. +82-32-821-0071 FAX. +82-32-821-0074 Internet: http://www.spident.co.kr
European representative:	AR EXPERTS B.V. (tradename: CE Medical) Amerlandseweg 7, 3621 ZC, Breukelen, the Netherlands TEL. +31 (0)85 007 32 20
Product:	VioPaste, Temporary root canal filling material
Classification:	Class IIa by Rule 7 of Annex IX, MDD 93/42/EEC as amended by 2007/47/EC
GMDN Code:	60275, Endodontic temporary cement
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 6876
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.