



EC Declaration of Conformity

Manufacturer	SPIDENT CO., LTD. 203, 304, 312, 314 & 315, Korea Industrial Complex, 722, Gojan-Dong, Namdong-Gu, Incheon, 405-821, Korea TEL. +82-32-821-0071 FAX. +82-32-821-0074 Internet: http://www.spident.co.kr	
SRN	KR-MF-000008691	
European representative	Certification Experts B.V. (tradenname: CE Medical) Amerlandseweg 7, 3621 ZC, Breukelen, the Netherlands TEL. +31 (0)85 007 32 20	
Basic UDI-DI	880926295FDZN	
Product Name	Light-Cured Liquid Dam	
Trade Name	FineDam, BARRERA GINGIVAL DE RESINA	
Product Code	MDN Code	1209
	MDS Code	N/A
	MDT Code	2006
Catalogue No.	FDS01R01/191202	
Intended purpose	FineDam is a light-reflecting resin barrier for isolating tissue adjacent to teeth being whitened. For single tooth bleaching, FineDam may be used to protect adjacent teeth.	



EC Declaration of Conformity

Classification	Class I based on Rule 5, Annex VIII, Regulation (EU) 2017/745
Common Specification	No Common Specification required
Conformity Assessment Route	Annex IV, Regulation (EU) 2017/745 on medical devices

We herewith declare that the under-mentioned products are in conformity with the general safety and performance requirements and provisions of Regulation (EU) 2017/745 on medical devices. All supporting documentation is retained under the premises of the manufacturer.

Place of Issue	Incheon, Korea
Date of Issue	May 20 2021



Signature:

A handwritten signature in black ink, appearing to read "Min Sung Kim", written over a horizontal line.

Min Sung Kim
Person Responsible for Regulatory Compliance
behalf of SPIDENT CO., LTD.