

## EU Declaration of Conformity

Name and address of the firm	Smile Line SA Rue de la Clef, 5 CH-2610 St. Imier Suisse
Single Registration Number (SRN)	CHRN-MF-20001413
Name and address of the Authorized Representative	Olivier Schaeren, CEO <a href="mailto:o.schaeren@smileline.ch">o.schaeren@smileline.ch</a>
European authorized representative:	SL Medirep SAS 22 avenue de la gare, F-25160 Labergement Ste Marie FRANCE SRN: FR-AR-000014715
Name, model and type of the Device	OPTISHADE & ACCESSORIES Art. n. 70100-OS Art n. 70110-OS; 70120-OS; 70130-OS
Swissmedic registration n°	CH-202104-0024
Basic UDI-DI	764019713OPTISHADEYR
Intended purpose	dental colorimeter for determining the shade of natural teeth & ceramic restorations
Risk Classification according to Annex VIII of the Regulation 2017/745	Class I, as per Rule 10 Class I, as per Rule 5 (accessories)
Harmonized Standards	EN ISO 13485:2016, EN ISO 14971:2019, EN-1639 2001/95/CE, 2014/35/CE, 2004/108/CE, 2011/65/UE 2006/66/CE, 2012/19/UE, TOS : EMC Directive 2004/108/EC TOS: LVD Directive 2014/35/EC

This declaration of conformity is issued under the sole responsibility of Smile Line.  
We hereby declare that the medical device(s) specified above meet all the provisions of the Regulation (EU) MDR 2017/745 for medical devices. The product fulfils the General Safety and Performance Requirements of the Regulation and conformity is assured according to the guidelines set out in Annex I.  
All supporting documentation is retained at the premises of the manufacturer.

Place and date of issue	Saint-Imier, 05.04.2023
Signature	
Name	Olivier Schaeren
Function	CEO

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