EC Declaration of Conformity

Manufacturer:	Firefly Global		
Address:	464 Common St, #281, Belmont, MA 02478, USA		
EU Representative:	MDSS GmbH		
Address:	Schiffgraben 41, 30175 Hannover, Germany		
Contact Tel:	+49 511 6262 8630		
Product(s):	Firefly Digital Dermatoscope	Model DE300	UDI-DI 851289007071
	Firefly Digital Trichoscope	Model DE330T	UDI-DI 851289007095
	Firefly Digital Trichoscope	Model DE337T	UDI-DI 851289007187
	Firefly Digital Dermatoscope	Model DE350	UDI-DI 851289007026
	Firefly Digital Dermatoscope	Model DE370	UDI-DI 851289007118
	Firefly General Exam Camera	Model DE605	UDI-DI 851289007033
Classification:	MDR 2017/745 Class 1		
Intended Use:	Clinical office-based medical diagnostic applications		

We, the manufacturer, herewith declare that the above mentioned product(s) meet the provisions of the Medical Device Regulation MDR 2017/745 and the RoHS Directive 2011/65/EU of the European Parliament and of the Council on the restriction of the use of certain hazardous substances in electrical and electronic equipment. The product(s) meet prospective uses and all supporting documentation is retained under the premise of the manufacturer and the notified body.

Applied Standards:

EN60601-1-2 & EN60601-1:	Medical electrical equipment – General requirements for basic safety and essential performance.
IEC 63000:2016:	Technical documentation for the evaluation of electrical and electronic products with respect to restriction of hazardous substances

Year of CE Marking: 2021

Place of Issue: Belmont, Massachusetts, USA

Manufacturer Signature:

Name: Dror Oved

Position: Vice President - Product Development

Date: January 6, 2021