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 Otoscope	Model DE500	UDI-DI 851289007064
	Firefly Digital Otoscope	Model DE550:	UDI-DI 851289007019
	Firefly Digital Otoscope	Model DE570 :	UDI-DI 851289007101

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:	2020
Place of Issue:	Belmont, Massachusetts, USA
Manufacturer Signature:	
Name:	Dror Oved
Position:	Vice President - Product Development
Date:	October 29, 2020