



## 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  
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**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