



## 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  
Trichoscope Firefly Digital Trichoscope Model DE301 UDI-DI 851289007095  
Dermatoscope Firefly Digital Dermatoscope Model DE302 UDI-DI 851289007187  
General Exam Camera Model DE350 UDI-DI 851289007026  
MDR 2017/745 Class 1 Model DE370 UDI-DI 851289007118  
Clinical office-based medical diagnostic applications Model DE605 UDI-DI 851289007033

**Classification:**

**Intended Use:**

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