



EC Declaration of Conformity

Manufacturer: Firefly Global
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EU Representative: MDSS GmbH
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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