



Certificate of Verification

Medical Device Safety Service GmbH (MDSS)

hereby declares that an Authorized Representative's Mandate according to the EU Regulation 2017/745 (MDR) is in place and that the following tasks have been carried out in accordance with the requirements of the MDR on behalf of the Manufacturer:

Firefly Global
464 Common Street #281
Belmont, MA 02478
USA

MDSS verified that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

MDSS keeps available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 56, at the disposal of competent authorities for the period referred to in Article 10(8);

MDSS complied with the registration obligations laid down in Article 123.3(d) and until Eudamed is fully functional, the corresponding provisions of Directives 90/385/EEC and/or 93/42/EEC have been applied.

Details of the device(s) covered by the Certificate are listed hereafter.

Issued: 2022-10-28
(YYYY-MM-DD)

This Certificate is valid without signature. The document can be traced within MDSS' electronic system.

Certificate No.: 623519

This certificate is subject to the following terms and conditions:

It is only valid for the device(s) listed hereafter;

It is not a proof for compliance to CE marking;

The Manufacturer shall inform MDSS of any significant change(s) to the device(s) listed hereafter and MDSS will verify the change(s) and determine if a renewed certificate has to be issued;

As in accordance with the Directive 85/374/EEC Art. 1, the producer is liable for damages caused by a defect in his product(s). The Manufacturer in addition confirms that the requirements of Art. 10.16 of the MDR are fulfilled.

This Certificate of Verification is valid for 5 years or until expiry of the EU Declaration of Conformity or NB Certificate if applicable, whichever comes first.

Technical File	Generic Device Description/ Trade Name	GMDN or CND Code	Risk Class	EU Declaration of Conformity	NB Identification No. / NB Certificate No.	NB Cert. valid until YYYY-MMDD	BfArM Registration Number*
TCF-001 Issued 11-06-2020	Firefly Digital Otoscope	N.A.	I	TCF-001-2 V1.5	N.A.	N.A.	DE/CA09/0170/F02/005
TCF-001 Issued 11-06-2020	Accessories to Firefly Digital Oscopes	N.A.	I	Replacement Parts V1.2	N.A.	N.A.	DE/CA09/0170/F02/005
TCF-002-1 Issued 24-10-2022	Firefly Digital Camera Redfin Digital Camera	N.A.	I	TCF-002-2 V1.9	N.A.	N.A.	DE/CA09/0170/F02/002-01
TCF-002 Issued 01-05-2021	Accessories to Firefly Digital Cameras,	N.A.	I	Replacement Parts V1.2	N.A.	N.A.	DE/CA09/0170/F02/002-01
TCF-003 Issued 01-05-2021	Firefly Compact Light Source	N.A.	I	TCF-003-2 V1.5	N.A.	N.A.	DE/CA09/0170/F02/001-01
TCF-006 Issued 01-05-2021	Firefly Digital Iris Scope	N.A.	I	TCF-006-2 V1.5	N.A.	N.A.	DE/CA09/0170/F02/002-01
TCF-009 Issued 01-05-2021	Firefly Digital Dermatoscopes; Trichoscopes; General Exam Cameras	N.A.	I	TCF-009-2 V1.5	N.A.	N.A.	DE/CA09/0170/F02/002-01 DE/CA09/0170/F02/004-03
TCF-009 Issued 01-05-2021	Accessories to Firefly Digital Dermatoscopes	N.A.	I	Replacement Parts V1.2	N.A.	N.A.	DE/CA09/0170/F02/002-01 DE/CA09/0170/F02/004-03

*The registration number has been issued by the German Competent Authority.