DECLARATION OF CONFORMITY

Product Identification

Medical Device Name(s):	Fiber Optic Endoscope Cables
EUDAMED Basic UDI-DI:	0857580006EC163
GMDN	35507
FDA PT Code:	PLFN – Fiberoptic Light Cable

Manufacturer

Name:	Gulf Fiberoptics, Inc
Address:	448 Commerce Blvd. Oldsmar, FL 34677, USA
Email:	contact@gulffiberoptics.com
Country of Manufacture:	United States of America
Manufacturer SRN:	US-MF-000006301
Representative:	Isabel Rengifo

Authorized Representative in EU

Name:	European Healthcare & Device Solutions Ltd Stratton House Bishopstown Road Cork, T12 79TC, Ireland
EU Country:	Ireland
AR SRN:	IE-AR-000003999

Authorized Representative in UK

European Device Solutions, Ltd.
15 Coanwood Dr.
Tyne & Wear,
Whitley Bay NE25 9GB
England, United Kingdom
N/A
N/A

Standards Applied

MDR 2017/745 IEC 60601-1 : ED3-2020	ISO 13485:2016 IEC 60601-2-18:2015	ISO 14971:2019 IEC 62366-1:2015

Notified Body

Name:	NOT APPLICABLE (Class I; Self-declaration device)
Address:	NOT APPLICABLE
EU Country:	NOT APPLICABLE

Means of Conformity

Gulf Fiberoptics, Inc. declares that the device listed above has been classified as:

Class I – Annex VIII, Rule 1, self-declaration

Gulf Fiberoptics, Inc. declares that the device(s) listed above meets the provisions of Regulation MDR 2017/745 for medical devices. All supporting documentation is retained under the premises of the manufacturer.

Company Approval

Signed: _____
(Quality Manager)

September 15, 2026
(Date)