DECLARATION OF CONFORMITY

Product Identification

Medical Device Name(s): Fiber Optic Endoscope Cables

EUDAMED Basic UDI-DI: 085758006EC163

FDA PT Code: PLFN – Fibreoptic 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: Scott Avoy

Authorized Representative in Europe

Name: European Healthcare & Device Solutions (Ireland) Ltd
Stratton House
Bishopstown Road
Cork, T12 79TC, Ireland

EU Country: Ireland
AR SRN: IE-AR-000003999

Standards Applied

MDR 2017/745	ISO 13485:2016	ISO 14971:2019
IEC 60601-1 : ED3-2020	IEC 60601-2-18:2015	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: 
(General Manager - Quality)

June 4, 2021
(Date)