

Declaration of Conformity

DC-01800-C

Manufacturer:	FUJIFILM Corporation
Address:	26-30, Nishiazabu 2-chome, Minato-ku, Tokyo 106-8620, JAPAN
Authorized Representative:	FUJIFILM Europe GmbH
Address:	Heesenstr. 31, 40549 Düsseldorf GERMANY
Product:	Air Leak Tester
Model No.:	LT-7F
UMDNS:	N/A
GMDN:	38460(Endoscope leak tester, mechanical)
Applicable Product Units:	Lot No. 1409 or later
Classification (MDD, Annex IX):	Class I (Rule 1)

We herewith declare in our own responsibility that the above mentioned product meets the provisions of the following EC Council Directive and Standards.

Directive:
Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC and RoHS Directive: 2011/65/EU

Standards:
Harmonized Standards (published in the Official Journal of the European Union) applicable to this product are:

EN ISO 13485:2012/AC:2012
EN ISO 14971:2012
EN 1041:2008
EN 62366:2008
EN 50581:2012

Conformity Assessment procedure under MDD 93/42/EEC: Annex VII

Signed for and on behalf of FUJIFILM Corporation

Place and Date of issue

Kanagawa, JAPAN

2014-05-16

Signature : 

Name : Naotake Mitsumori

Function : Senior Manager,
Quality Assurance and Regulatory Affairs Division,
Medical Systems Business Division
FUJIFILM Corporation