DECLARATION OF CONFORMITY

Application of Council Directive(s):	93/42/EEC, as amended by 2007/47/EC
Standard(s) to which conformity is declared:	ISO 13485: 2016 MDD Annex II
Notified Body:	LRQA UK (0088) 1 Trinity Park Bickenhill Lane Birmingham B37 7ES United Kingdom
Manufacturer:	**LeMaitre Vascular Inc.**
Manufacturer Address:	63 Second Avenue Burlington, Massachusetts 01803, U.S.A
Name of Device:	**VascuTape Radiopaque Tape** (LeMaitre Glow 'N Tell Tape, LeMaitre Stent Guide)
Intended Use:	VascuTape is a flexible, medical-grade tape for use during any vascular procedure involving fluoroscopy or radiography. VascuTape can be used for stent placements, identifying fistula locations, PTA procedures during in situ bypass grafting, vena cava filter placement, atherectomy, and balloon catheter insertions.
Device Classification:	Class I Sterile and Measuring
Type No. / Model No. / Ref. No.	Glow N' Tell Tape-1100-00, 1100-01, 1100-20, 1100-50 Glow N' Tell 55cm Tape-1108-00, 1108-20, 1108-50 LeMaitre Stent Guide-1102-00, 1102-20, 1102-50 LeMaitre 550mm Stent Guide-1109-01, 1109-20, 1109-50, 1112-20
EU Authorized Representative:	LeMaitre Vascular GmbH Otto-Volger-Str. 5a/b 65843, Sulzbach/Ts Germany

I, the undersigned, hereby declare that the medical device(s) specified above conform with the Essential Requirements listed in Annex I of the European Council Directive 93/42/EEC dated 14 June 1993 concerning medical devices

Place: LeMaitre Vascular Inc.
63 Second Avenue
Burlington, MA 01803 U.S.A.

Xiang (Vic) Zhang, Vice President of Regulatory Affairs

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