EC DECLARATION OF CONFORMITY

RF 19-0044 Rev. C
DC Number: DC20-03704

We, MicroVention Europe SARL, located in Saint-Germain-en-Laye, France, declare according to Directive 93/42/EEC Annex II under our sole responsibility that the products to which this declaration relates are in conformity with Directive 93/42/EEC and fulfill the Essential Requirements as described in Directive 93/42/EEC Annex I.

Council Directive 93/42/EEC

Conformity Assessment Procedure Performed:

EC Design Examination Certificate ☒ (Annex II.4) 490690 MRA **Certificate Number**	**EC Full Quality Assurance Certificate** ☒ (Annex II.3) 487703 MR2 **Certificate Number**

Product	Model Number(s)	Class/Rule	GMDN Code
LVIS™ Intraluminal Support Device LVIS™ Jr. Intraluminal Support Device LVIS™ EVO™ Intraluminal Support Device LVIS™ X™ Intraluminal Support Device LVIS™ Jr. X™ Intraluminal Support Device LVIS™ EVO™ X™ Intraluminal Support Device	*See attached list*	Class III – Annex IX, Rule 8 Subclause 2	46352

Legal Manufacturer	Production Site(s)	Notified Body
MicroVention Europe SARL 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye France	MicroVention, Inc. 1311 Valencia Avenue Tustin, California 92780 USA MicroVention Costa Rica, S.R.L. Zona Franca Coyol Alajuela, Costa Rica MicroVention, Inc. 35 Enterprise Aliso Viejo, California 92656 USA	DQS Medizinprodukte GmbH D-60433 Frankfurt am Main, Germany Notified Body No: 0297

We herewith declare that the above-mentioned medical device (s) meet the provisions of the council directive 93/42/EEC Medical Device Directive. This declaration is supported by the EC Quality System Certificate (s) according to the provisions of the relevant Annex (es) of above Directive. This declaration applies to all device(s) specified above distributed from the signature date forward.

D. Kulinets

Irina Kulinets
Sr. Vice President, Regulatory Affairs,
Quality, Clinical Research
MicroVention Europe SARL

Saint-Germain-en-Laye, France
Place of Issue

6/23/2020
Date of Issue

Certificate Expiry Date: 26 May 2024

LVIS Intraluminal Support Device Product Family

MicroVention Europe SARL au capital de 40.000 Euros R.C.S. Versailles B 440 775 674 00029 – APE 4646Z
Siège Social : 30 bis, rue du Vieil Abreuvoir – 78100 Saint-Germain-en-Laye
Etablissement Secondaire (pour toutes correspondances et livraisons) 20 Quater rue Schnapper – 78100 Saint-Germain-en-Laye
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MicroVention TERUMO

EC DECLARATION OF CONFORMITY

LVIS Model Numbers			
212517-CAS	212912-CAS	213015-CAS	214035-CAS
212525-CAS	212917-CAS	213025-CAS	214049-CAS
213517-CAS	212922-CAS	213041-CAS	215530-CAS
213522-CAS	212928-CAS	214518-CAS	215533-CAS
	212931-CAS	214523-CAS	
	214012-CAS	214532-CAS	
	214017-CAS		
	214022-CAS		
	214028-CAS		
	214031-CAS		
LVIS X Model Numbers			
212517-XCAS	212912-XCAS	213015-XCAS	214035-XCAS
212525-XCAS	212917-XCAS	213025-XCAS	214049-XCAS
	212922-XCAS	213041-XCAS	
	212928-XCAS		
	212931-XCAS		
LVIS Jr Model Numbers			
172010-CASJ		172516-CASJ	
172014-CASJ		172524-CASJ	
172020-CASJ		172530-CASJ	
172032-CASJ		172537-CASJ	
LVIS Jr X Model Numbers			
172010-XCASJ		172516-XCASJ	
172014-XCASJ		172524-XCASJ	
172020-XCASJ		172530-XCASJ	
172032-XCASJ		172537-XCASJ	
LVIS EVO Model Numbers			
LEV2512	LEV3018	LEV3517	LEV4013
LEV2517	LEV3024	LEV3522	LEV4018
LEV2522	LEV3028	LEV3528	LEV4021
LEV2527	LEV3032	LEV3534	LEV4027
			LEV4031
LVIS EVO X Model Numbers			
XLEV2512	XLEV3018	XLEV3517	XLEV4013
XLEV2517	XLEV3024	XLEV3522	XLEV4018
XLEV2522	XLEV3028	XLEV3528	XLEV4021
XLEV2527	XLEV3032	XLEV3534	XLEV4027
			XLEV4031

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