

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
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Product	Model Number(s)	Class/Rule	GMDN Code
LVIST™ Intraluminal Support Device LVIST™ Jr. Intraluminal Support Device LVIST™ EVO™ Intraluminal Support Device LVIST™ XT™ Intraluminal Support Device LVIST™ Jr. XT™ Intraluminal Support Device LVIST™ EVO™ XT™ 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.

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Place of Issue

6/23/2020

Date of Issue

Certificate Expiry Date: 26 May 2024

LVIS Intraluminal Support Device Product Family

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