

EC DECLARATION OF CONFORMITY

FD12-0034 / N

We, MicroVention Europe, located in Saint-Germain-en-Laye, France declare according to Directive 93/42/EEC Annex II (incl. section 4.) 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.

Directives: 93/42/EEC Council Directive Concerning Medical Devices
 Conformity Assessment Route:
 EC Design Examination: 490690 MRA (Section 4)
 Full Quality Assurance: 487703 MR2 (Excluding Section 4)

Product	Model Number(s)	Class-Rule	Effectivity date	GMDN code
LVIS Intraluminal Support Device	212517-CAS 212931-CAS 212525-CAS 213015-CAS 212912-CAS 213025-CAS 212917-CAS 213041-CAS 212922-CAS 214035-CAS 212928-CAS 214049-CAS	III – Annex 9, rule 8	2018-04-30	46352
LVIS Jr. Intraluminal Support Device	172010-CASJ 172516-CASJ 172014-CASJ 172524-CASJ 172020-CASJ 172530-CASJ 172032-CASJ 172537-CASJ			

Manufacturer

MicroVention Europe
 30 bis, rue du Vieil Abreuvor
 78100 Saint-Germain-en-Laye
 France

Notified Body

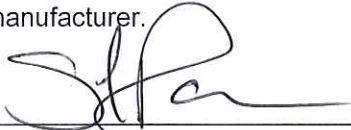
DQS Medizinprodukte GmbH
 Notified Body Number: 0297
 D-60433 Frankfurt am Main,
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Production Site

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MicroVention, Inc.
 35 Enterprise
 Aliso Viejo, CA 92656, USA
MicroVention Costa Rica, S.R.L.
 Zona Franca Coyol
 Alajuela, Costa Rica

Intended Use: The LVIS and LVIS Jr. devices are intended for use with embolic coils for the treatment of intracranial neurovascular diseases.

We herewith declare that the above-mentioned products meet the provisions of the council directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.



Salvador Palomares
 Director, Regulatory Affairs
 MicroVention Europe

Saint-Germain-en-Laye

Place of Issue

11 July 2018

Date of Issue

Expiry Date: 2020-12-29

Prepared for Romania
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