

EC DECLARATION OF CONFORMITY

FD14-0031, Rev. F

We, MicroVention Europe SARL, 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:

517356 MRA Annex II (Section 4)

Full Quality Assurance:

487703 MR2 Annex II (Excluding Section 4)

Product	Model Number(s)	Class-Rule	Effectivity date	GMDN code
PHIL™ Liquid Embolic System	LEN10250 LEN10250RE LEN10300 LEN10300RE LEN10350 LEN10350RE LEN10LV250 LEN10LV250RE	III – Annex 9, rule 8	2018-11-06	60939

Manufacturer	Notified Body	Production Site
MicroVention Europe SARL 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye France	DQS Medizinprodukte GmbH Notified Body Number: 0297 D-60433 Frankfurt am Main, Germany	MicroVention, Inc. 1311 Valencia Avenue Tustin, CA 92780 USA MicroVention, Inc. 35 Enterprise Aliso Viejo, CA 92656 USA

Intended Use: The PHIL™ Liquid Embolic System is intended for use in the embolization of lesions in the peripheral and neurovasculature, including arteriovenous malformations and hypervascular tumors.

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.



Salvadore Palomares
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MicroVention Europe SARL

Saint-Germain-en-Laye

Place of Issue

21-JAN-2019

Date of Issue

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