EC DECLARATION OF CONFORMITY

FD08-001, Rev. R

We, MicroVention, Inc., located in Tustin, California, USA 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:	411133 MRA (Section 4)
Full Quality Assurance:	411133 MR2 (Excluding Section 4)

Product	Model Number(s)	Class-Rule	Effectivity date	GMDN code
Traxcess 14 Guidewire*	GW1420040	III – Annex IX, Rule 7, Subclause 1	2018-05-27	35094
Traxcess 14EX Guidewire*	GW1420040X			
Traxcess 14 SELECT Guidewire	GW1420040S			
Traxcess 7 Mini	GW0721006M			
Traxcess 7 Mini XSoft	GW0721006S			
Traxcess Docking Wire*	GW14100EX	IIa- Annex IX, Rule 7		61281

Manufacturer/ Production Site:
MicroVention Inc,
1311 Valencia Avenue
Tustin, CA 92780 USA

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

EU Representative:
MicroVention Europe
30 bis, rue du Vieil Abreuvoir
78100 Saint-Germain-en-Laye
France

Production Site:
Ashitaka Factory of Terumo Corp. *
150 Maimaigi-Cho
Fujinomiya, Sizuoka Japan

Intended Use: The Traxcess Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The wire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.

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.

Sal Palomares
Regulatory Affairs Director
MicroVention, Inc.

Tustin, CA 92780, USA
Place of Issue

28 June 2018
Date of Issue

Expiry Date: 2023-05-26
Prepared for Romania

Digitally signed by Grabazei Alexandru
Date: 2021.12.20 22:22:14 EET
Reason: MoldSign Signature
Location: Moldova

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