

EC DECLARATION OF CONFORMITY

RF 19-0025 Rev. B

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 ☒ <u>(Annex II.4)</u> <u>502357 MRA</u> Certificate Number	EC Full Quality Assurance Certificate ☒ <u>(Annex II.3)</u> <u>487703 MR2</u> Certificate Number
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Product	Model Number(s)	Class/Rule	GMDN Code
FRED® Flow Re-Direction Endoluminal Device FRED® Jr. Flow Re-Direction Endoluminal Device FRED® X™ Flow Re-Direction Endoluminal 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

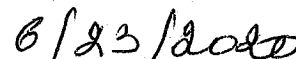
We herewith declare that the above-mentioned medical device (s) meet the provisions of the council directive 93/42/EEC Medical Device Directive. This declaration is supported by the EC Quality System Certificate (s) according to the provisions of the relevant Annex (es) of above Directive. This declaration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



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

Saint-Germain-en-Laye,
France

Place of Issue



Date of Issue

Certificate Expiry Date: 26 May 2024

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FRED, FRED Jr and FRED X Flow Re-Direction Endoluminal Device Model Numbers

FRED			
FRED3507	FRED4007	FRED4508	FRED5009
FRED3509	FRED4009	FRED4511	FRED5011
FRED3511	FRED4012	FRED4513	FRED5014
FRED3513	FRED4014	FRED4518	FRED5019
FRED3516	FRED4017	FRED4524	FRED5026
FRED3524	FRED4026	FRED4528	FRED5029
FRED3536	FRED4038	FRED4539	FRED5514
			FRED5519
			FRED5526
FRED Jr.			
FREDJR2508	FREDJR2518	FREDJR3009	FREDJR3019
FREDJR2509	FREDJR2519	FREDJR3010	FREDJR3020
FREDJR2510	FREDJR2520	FREDJR3011	FREDJR3021
FREDJR2511	FREDJR2521	FREDJR3012	FREDJR3022
FREDJR2512	FREDJR2522	FREDJR3013	FREDJR3023
FREDJR2513	FREDJR2523	FREDJR3014	FREDJR3024
FREDJR2514	FREDJR2524	FREDJR3015	FREDJR3025
FREDJR2515	FREDJR2525	FREDJR3016	FREDJR3026
FREDJR2516	FREDJR2526	FREDJR3017	FREDJR3027
FREDJR2517		FREDJR3018	
FRED X			
XFRED3507	XFRED4007	XFRED4508	XFRED5009
XFRED3509	XFRED4009	XFRED4511	XFRED5011
XFRED3511	XFRED4012	XFRED4513	XFRED5014
XFRED3513	XFRED4014	XFRED4518	XFRED5019
XFRED3516	XFRED4017	XFRED4524	XFRED5026
XFRED3524	XFRED4026	XFRED4528	XFRED5029
XFRED3536	XFRED4038	XFRED4539	XFRED5514
			XFRED5519
			XFRED5526
XFRED2508	XFRED2518	XFRED3009	XFRED3019
XFRED2509	XFRED2519	XFRED3010	XFRED3020
XFRED2510	XFRED2520	XFRED3011	XFRED3021
XFRED2511	XFRED2521	XFRED3012	XFRED3022
XFRED2512	XFRED2522	XFRED3013	XFRED3023
XFRED2513	XFRED2523	XFRED3014	XFRED3024
XFRED2514	XFRED2524	XFRED3015	XFRED3025
XFRED2515	XFRED2525	XFRED3016	XFRED3026
XFRED2516	XFRED2526	XFRED3017	XFRED3027
XFRED2517		XFRED3018	