

EC DECLARATION OF CONFORMITY

RF20-0022 Rev. B
ECN Number: 22-03348

We, MicroVention, Inc., located in Aliso Viejo, California, USA, 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>Not applicable</u> Certificate Number	EC Full Quality Assurance Certificate ☒ <u>(Annex II.3)</u> <u>411133 MR2 (Excluding Section 4)</u> Certificate Number
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Product	Model Number(s)	Class/Rule	GMDN Code
AZUR™ Peripheral Coil System	Refer to Table 1 below	Class IIb, Annex 9, Rule 8	60941

Legal Manufacturer	Production Site(s)	Notified Body	EU Representative
MicroVention, Inc. 35 Enterprise Aliso Viejo, CA 92656 United States of America	MicroVention, Inc. 35 Enterprise Aliso Viejo, CA 92656 USA MicroVention Costa Rica SRL Zona Franca Coyol Alajuela, Costa Rica	DQS Medizinprodukte GmbH D-60433 Frankfurt am Main, Germany Notified Body No: 0297	MicroVention Europe SARL 30 bis, rue du Vieil Abreuvoir 78100 Saint-Germain-en-Laye France

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.

DocuSigned by:
Amy Smith

Signer Name: Amy Smith
Signing Reason: I approve this document
Signing Time: 8/24/2022 | 3:24:57 PM PDT
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Amy Smith VP, Global Regulatory Affairs MicroVention, Inc.	Aliso Viejo, CA, USA Place of Issue	8/24/2022 Date of Issue
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Certificate Expiry Date: 2024-05-26

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Table 1. Azur Model Numbers

Azur™ 18 Detachable Peripheral Coil System Helical HydroCoil™ Embolization System		
45-480202	45-480510	45-481015
45-480204	45-480515	45-481020
45-480302	45-480520	45-481215
45-480305	45-480610	45-481220
45-480310	45-480615	45-481515
45-480405	45-480620	45-481520
45-480410	45-480810	45-481530
45-480415	45-480815	45-482020
45-480420	45-480820	45-482030
45-480505	45-481010	
Azur™ 35 Detachable Peripheral Coil System Helical HydroCoil™ Embolization System		
45-450305	45-450610	45-451215
45-450405	45-450615	45-451220
45-450410	45-450620	45-451230
45-450415	45-450815	45-451520
45-450505	45-450820	45-451530
45-450510	45-451015	45-452020
45-450515	45-451020	45-452030
Azur™ 18 Detachable Peripheral Coil System Framing Coil		
45-680410	45-680923	45-681434
45-680512	45-681026	45-681639
45-680615	45-681128	45-681844
45-680717	45-681231	45-682050
45-680820	45-681332	
Azur™ 35 Detachable Peripheral Coil System Framing Coil		
45-650820	45-651434	45-652050
45-651026	45-651639	
45-651231	45-651844	
Azur™ CX18 Detachable Peripheral Coil System CX Coil		
45-780202	45-780620	45-781238
45-780204	45-780724	45-781434
45-780304	45-780828	45-781639
45-780308	45-780928	45-781836
45-780413	45-781032	45-782040
45-780516		
Azur™ CX35 Detachable Peripheral Coil System CX Coil		
45-750407	45-750812	45-751632
45-750511	45-750824	45-752039
45-750609	45-751019	
45-750617	45-751324	
AZUR™ 18 Pushable Peripheral Coil System		
45-280202	45-280506	45-280810
45-280302	45-280510	45-280814
45-280304	45-280514	45-280820
45-280402	45-280606	45-281014
45-280404	45-280610	45-281020
45-280406	45-280614	
45-280504	45-280620	
AZUR™ 35 Pushable Peripheral Coil System		
45-250304	45-250610	45-251014
45-250404	45-250614	45-251020
45-250406	45-250806	45-251514
45-250504	45-250810	45-251520
45-250506	45-250814	45-251614
45-250510	45-250820	45-251620
45-250606	45-251010	