

EC DECLARATION OF CONFORMITY

RF19-0078 Rev. D
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 <input checked="" type="checkbox"/> <u>(Annex II.4)</u> <hr/> 411133 MRA Certificate Number	EC Full Quality Assurance Certificate <input checked="" type="checkbox"/> <u>(Annex II.3)</u> <hr/> 411133 MR2 Certificate Number
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Product	Model Number(s)	Class/Rule	GMDN Code
Traxcess 14 Guidewire*	GW1420040	Class III, Annex 9, Rule 7	35094
Traxcess 14EX Guidewire*	GW1420040X		
Traxcess 14 SELECT Guidewire	GW1420040S		
Traxcess 7 Mini	GW0721006M		
Traxcess 7 Mini XSoft	GW0721006S		
Traxcess Docking Wire*	GW14100EX	Class IIa, Annex 9, Rule 7	61281

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 *Ashitaka Factory of Terumo Corp. 150 Maimaigi-Cho Fujinomiya, Sizuoka Japan	DQS Medizinprodukte GmbH D-60433 Frankfurt am Main, Germany Notified Body No: 0297	MicroVention Europe SARL 30 bis, rue du Vieil Abrevoir 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.

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DocuSigned by:
Amy Smith
Signer Name: Amy Smith
Signing Reason: I approve this document
Signing Time: 8/24/2022 | 3:15:49 PM PDT
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Aliso Viejo, CA, USA

8/24/2022

Amy Smith
VP, Global Regulatory Affairs
MicroVention, Inc.

Place of Issue

Date of Issue

Certificate Expiry Date: 2024-05-26