

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> 411133 MRA Certificate Number | EC Full Quality Assurance Certificate <input checked="" type="checkbox"/> <u>(Annex II.3)</u> 411133 MR2 Certificate Number |
|--|--|

| 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 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.

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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