

EC DECLARATION OF CONFORMITY

RF18-0182D

We, MicroVention, Inc., located in Tustin, 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> 494215 MRA Certificate Number	EC Full Quality Assurance Certificate <input checked="" type="checkbox"/> <u>(Annex II.3)</u> 411133 MR2 Certificate Number
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Product	Model Number(s)	Class/Rule	GMDN Code
Scepter XC Scepter C Scepter Mini	BC0411XC BC0410C BC0415C BC0420C BC0210M	III – Annex 9, rule 8	32584

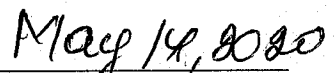
Legal Manufacturer	Production Site(s)	Notified Body	EU Representative
MicroVention, Inc. 1311 Valencia Ave. Tustin, CA, 92780 United States of America	MicroVention, Inc. 35 Enterprise, Aliso Viejo, CA 92656, USA MicroVention, Inc. 1311 Valencia Ave. Tustin, CA 92780, USA MicroVention Costa Rica, S.R.L. 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.



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

Tustin, CA, USA
Place of Issue



Date of Issue

Certificate Expiry Date: 2024-05-26