

MicroVention, Inc
35 Enterprise
Aliso Viejo
92656 USA

Our ref.: CAB, Phone: 069 95427-8211, Fax: -388
E-Mail: carrie-ann.brown@dqs-med.de

Frankfurt a. M.
2022-07-21

Certification confirmation letter

To whom it may concern,

DQS Medizinprodukte GmbH is a Notified Body according to § 15 Medical Devices Act – Directive 93/42/EEC and according to Regulation (EU) 2017/745 on medical devices. After 25th May 2021, Regulation (EU) 2017/745 superseded Directive 93/42/EEC.

We as a Notified Body will continue to perform the surveillance activities for certificates according to Directive 93/42/EEC issued by DQS Medizinprodukte GmbH, which are still valid.

DQS Medizinprodukte GmbH is registered as NB 0297.

Furthermore, DQS Medizinprodukte GmbH is an accredited certification body for management systems under the terms of DIN EN ISO/IEC 17021-1:2015 to carry out certifications of management systems according to DIN EN ISO 13485:2016.

DQS Medizinprodukte GmbH hereby confirms that the EC-Certificate (Certificate registration no. 411133MR2 with the unique certification ID 170776096 valid from 2021-04-29 until 2024-05-26) and the **corresponding EC Design Examination certificates for class III medical devices** have been issued to the following auditee:

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in accordance with Annex II excluding section 4 of Council Directive 93/42/EEC concerning medical devices.



DQS Medizinprodukte as the Notified Body hereby acknowledges that the Address of MicroVention, Inc, 1311 Valencia Ave.Tustin, CA, 92780 United States of America has been changed to 35 Enterprise, Aliso Viejo, 92656 United States of America as of 22.06.2022. The existing **Annex II and EC Design Examination certificates** remain valid per this confirmation letter.

Yours faithfully,
DQS Medizinprodukte GmbH

A handwritten signature in blue ink, appearing to read 'J. Emakam'. The signature is written in a cursive, flowing style.

i.A. Francine Emakam
Regulatory Affairs Manager