DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

Ascyrus Medical GmbH (a part of Artivion, Inc.)
Grosse Gallusstrasse 16-18
60312 Frankfurt am Main

Our ref.: DHE, phone: +49 69 95427-8158
E-Mail: David.Heil@dqs-med.de

Frankfurt a. M.
15th December 2023

Change in the address of the manufacturer Ascyrus Medical GmbH

To whom it may concern,

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 After 25th May 2021, Regulation (EU) 2017/745 superseded Directive 93/42/EEC.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

DQS confirms that Ascyrus Medical GmbH communicated the following change in a timely manner (December 22nd of 2022) and the certification process and audit plan were adapted. An extensive assessment took place as described below.

The Ascyrus Medical GmbH former legal manufacturer address is Bethmannstrasse 8, 60311 Frankfurt am Main.

The official legal manufacturer address for Ascyrus Medical GmbH is changed to the following address:

Grosse Gallusstrasse 16-18
60312 Frankfurt am Main

The address change was assessed during an audit in calendar week 38 of 2023. It was an extensive assessment with the effort of a recertification audit. An auditor of DQS MED was on-site in Grosse Gallusstrasse 16-18, 60312 Frankfurt am Main on the 21st and 22nd of September 2023. The new address could be verified. An auditor was located at the critical supplier Medical Murray 19th to 22nd of September 2023 and there was the possibility for the audit team to connect via videoconference. The organization showed overall compliance during the audit and the documentation of the audit was approved internally by DQS MED.

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Due to the transition period from MDD 93/42/EEC to Regulation (EU) 2017/745, DQS Medizinprodukte GmbH cannot change a certification according to Directive 93/42/EEC. Hence, the address on the certificates remain the same. The new address supersedes the old one, which is subject to confirmation during the audit.

DQS Medizinprodukte GmbH hereby confirms that the certificates:

Company	**Type of Certificate**	**Certification Registration No.**	**Certificate Unique ID**
Ascyrus Medical GmbH	EC Design Examination Certificate Council Directive 93/42/EEC Annex II Section 4	536309 MRA	170759202
Ascyrus Medical GmbH	Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices	536309 MR2	170758979

issued for the company

Ascyrus Medical GmbH
Bethmannstrasse 8
60311 Frankfurt am Main
Germany

are true and valid copies of the original certificate, issued by the Notified Body DQS Medizinprodukte GmbH, headquartered in August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany.
The above-mentioned certificates cover the products and quality assurance system listed on the certificates.

Yours faithfully,
DQS Medizinprodukte GmbH

[redacted]

On behalf of David Heil
Regulatory Affairs Manager

[redacted]

On behalf of Dr. Daniel Siuda
Regulatory Affairs Manager