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

Ascyrus Medical GmbH
Bethmannstrasse 8
60311 Frankfurt am Main

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

Frankfurt a. M.
03th Aug 2021

Change in the name of the product from the Ascyrus Medical Dissection Stent (AMDS) to the Ascyrus Medical Dissection Stent Hybrid Prosthesis

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 § 15 Medical 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 After 25th May 2021, Regulation (EU) 2017/745 superseded Directive 93/42/EEC.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.
Find attached the confirmations of our notification according to Directive 93/42/EEC and Regulation (EU) 2017/745, as provided on the NANDO database.

Ascyrus Medical GmbH requested a name change to the certificates mentioned on the next page. The name of the product should be “Ascyrus Medical Dissection Stent Hybrid Prosthesis” instead of “Ascyrus Medical Dissection Stent”.
DQS Medizinprodukte GmbH approves that the medical device can be referred to as “Ascyrus Medical Dissection Stent Hybrid Prosthesis” in marketing material and all other documentation provided with the product.
However, due to the transition period from MDD 93/42/EEC to VO (EU) 2017/745, DQS Medizinprodukte GmbH cannot change a certification according to Directive 93/42/EEC. Hence, the names on the certificates remain the same, but the new name is considered valid and supersedes the old one.

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
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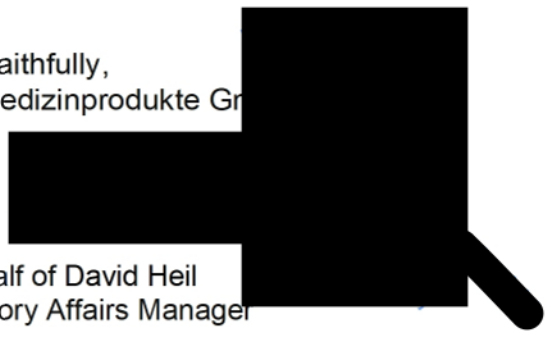
are true and valid copies of the original certificate, issued by the Notified Body DQS Medizinprodukte GmbH, headquartered in August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany.

The above-mentioned certificates cover the products and quality assurance system listed on the attached certificates.

Yours faithfully,
DQS Medizinprodukte Gr



On behalf of David Heil
Regulatory Affairs Manager