

## Declaration of Conformity

<b>Manufacturer:</b>	<b>Ascyrus Medical GmbH</b>		
<b>Address:</b>	Ascyrus Medical GmbH Grosse Gallusstrasse 16-18 60312 Frankfurt, Germany		
<b>Product:</b>	Ascyrus Medical Dissection Stent Hybrid Prosthesis		
<b>Model/Item Numbers:</b>	see page 2		
<b>Classification:</b>	Class III according to Annex IX of the Council Directive MDD 93/42/EEC, rule 8		
<b>UMDNS:</b>	17461, vascular stent, Nitinol		
<b>GMDN:</b>	43521 Bare-metal aortic stent		
	We herewith declare that the above-mentioned products meet the essential requirements of the following EC Council Directives and Standards. All supporting documentation is retained under the premises of the manufacturer and the notified body. Ascyrus Medical GmbH is exclusively responsible for this Declaration of Conformity.		
<b>Conformance:</b>	Conformance to Annex II of Council Directives 93/42/EEC		
<b>Notified Body:</b>	DQS Medizinprodukte GmbH (Identification Number 0297) August-Schanz-Straße 21 60433 Frankfurt am Main Germany		
<b>Certificates</b>	<b>Certificate Type</b>	<b>Certificate Registration Number</b>	<b>Validity</b>
	EN ISO 13485:2016 + AC :2017-07	536309 MP2016	Valid until 2024-06-16
	MDD Annex II, excluding section 4	536309 MR2	Valid until 2024-01-27
	MDD Annex II, section 4	536309 MRA	Valid until 2024-01-27
	Certificate Letter Name Change	DQS Letter	Valid from 2021-08-03
<b>Validity:</b>	This declaration of conformity is valid for all products included in this declaration manufactured after the issue date of this declaration.		
<b>Place, Date:</b>	Kennesaw, Georgia, USA 09 August 2023 Issue 7 Date CE mark was approved to be affixed: 2019-01-28		
<b>Signature:</b>			
<b>Name:</b>	Drew Green		
<b>Position:</b>	Managing Director		

Model/Item Numbers:

Device	Item Number*	Proximal Aorta Diameter (mm)	Distal Aorta Diameter (mm)	Unit Length at Minimum IFU Diameter (mm)	Unit Length at Maximum IFU Diameter (mm)
<b>AMDS 40-30 tapered</b>	AMDS4030-XX	20-35	20-24	210 mm	170 mm
<b>AMDS 40</b>	AMDS40-XX	20-35	25-35	208 mm	155 mm
<b>AMDS 55-40 tapered</b>	AMDS5540-XX	36-45	27-35	225 mm	190 mm
<b>AMDS 55</b>	AMDS55-XX	36-45	36-45	231 mm	195 mm

\*two-character country specific National Code (-xx) per [http://www.nationsonline.org/oneworld/country\\_code\\_list.htm](http://www.nationsonline.org/oneworld/country_code_list.htm), see Annex on page 3 of this Declaration of Conformity

Annex

Item Numbers With And Without Two-Character Country Specific National Code (-xx)

[http://www.nationsonline.org/oneworld/country\\_code\\_list.htm](http://www.nationsonline.org/oneworld/country_code_list.htm)

Item Number	Item Number without country code
AMDS4030-XX	AMDS4030
AMDS40-XX	AMDS40
AMDS5540-XX	AMDS5540
AMDS55-XX	AMDS55

Item Number with country code -DE	Item Number with country code -GB	Item Number with country code -NL	Item Number with country code -ES	Item Number with country code -LA	Item Number with country code -RE
AMDS4030-DE	AMDS4030-GB	AMDS4030-NL	AMDS4030-ES	AMDS4030-LA	AMDS4030-RE
AMDS40-DE	AMDS40-GB	AMDS40-NL	AMDS40-ES	AMDS40-LA	AMDS40-RE
AMDS5540-DE	AMDS5540-GB	AMDS5540-NL	AMDS5540-ES	AMDS5540-LA	AMDS5540-RE
AMDS55-DE	AMDS55-GB	AMDS55-NL	AMDS55-ES	AMDS55-LA	AMDS55-RE

**Certificate Of Completion**

Envelope Id: 326C319B33024E7B9980F4E3A52D9C1A	Status: Completed
Subject: Complete with DocuSign: AMDS_DoC_Issue7.pdf	
Source Envelope:	
Document Pages: 3	Signatures: 1
Certificate Pages: 1	Initials: 0
AutoNav: Enabled	Envelope Originator:
Envelope Stamping: Disabled	Lauren Livsey
Time Zone: (UTC-05:00) Eastern Time (US & Canada)	1655 Roberts Blvd. NW
	Kennesaw, GA 30144
	lauren.livsey@artivion.com
	IP Address: 45.23.88.215

**Record Tracking**

Status: Original	Holder: Lauren Livsey	Location: DocuSign
8/9/2023 8:08:52 AM	lauren.livsey@artivion.com	

**Signer Events**

Drew Green  
drew.green@artivion.com  
VP, Regulatory Affairs  
Security Level: Email, Account Authentication (Required)

**Signature**



Signature Adoption: Pre-selected Style  
Signature ID:



With Signing Authentication via DocuSign password  
With Signing Reasons (on each tab):  
I approve this document

**Timestamp**

Sent: 8/9/2023 8:12:08 AM  
Viewed: 8/9/2023 8:13:27 AM  
Signed: 8/9/2023 8:13:41 AM

**Electronic Record and Signature Disclosure:**  
Not Offered via DocuSign

**In Person Signer Events**

**Signature**

**Timestamp**

**Editor Delivery Events**

**Status**

**Timestamp**

**Agent Delivery Events**

**Status**

**Timestamp**

**Intermediary Delivery Events**

**Status**

**Timestamp**

**Certified Delivery Events**

**Status**

**Timestamp**

**Carbon Copy Events**

**Status**

**Timestamp**

**Witness Events**

**Signature**

**Timestamp**

**Notary Events**

**Signature**

**Timestamp**

**Envelope Summary Events**

**Status**

**Timestamps**

Envelope Sent	Hashed/Encrypted	8/9/2023 8:12:08 AM
Certified Delivered	Security Checked	8/9/2023 8:13:27 AM
Signing Complete	Security Checked	8/9/2023 8:13:41 AM
Completed	Security Checked	8/9/2023 8:13:41 AM

**Payment Events**

**Status**

**Timestamps**