



EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

Ascyrus Medical GmbH

Bethmannstrasse 8
60311 Frankfurt
Germany

that the design of the following device(s)

Ascyrus Medical Dissection Stent as listed according to annex

is conform to the Essential Requirements of Annex I of the Council Directive 93/42/EEC concerning medical devices.

This EC Design Examination Certificate is only valid in connection with the valid DQS Medizinprodukte GmbH Certificate No. 536309 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: Ascyrus Medical Dissection Stent dated 2019-01-23
Change Notification dated 2019-06-19

Further basis for the examination is referenced in the examination report and relating documents mentioned below.

Examination report: 19_411_18e_Report_DesignExaminationAZ_536309_V3 dated 2019-01-27
411_18e_Report_Change NotificationAZ536309_V3_2019-08-07.docx dated 2019-08-23

The results of the examination are contained in the above mentioned report and the relating documents mentioned within.

Certificate registration no.	536309 MRA
Certificate unique ID	170759202
Effective date	2019-12-05
Expiry date	2024-01-27
Frankfurt am Main	2019-12-05

DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



Annex to certificate
Certificate registration No.: 536309 MRA
Certificate unique ID: 170759202
Effective date: 2019-12-05

Ascyrus Medical GmbH

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Device

AMDS 40-30 tapered
AMDS 40
AMDS 40-30 tapered (Classic)
AMDS 40 (Classic)

AMDS 55-40 tapered
AMDS 55
AMDS 55-40 tapered (Classic)
AMDS 55 (Classic)