EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

Acandis GmbH

Theodor-Fahrner-Strasse 6
75177 Pforzheim
Germany

that the design of the following device(s)

Acclino® Stent System as listed according 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. 516802 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination:	STED_CE-Approval_Acclino flex Stent-E_A STED_CE_Approval_Acclino flex plus Stent-E_A dated 2018-09-28 Further basis for the examination is referenced in the examination report and relating documents mentioned below.
Examination report:	411_18E_Report_TFR_Acclino_V1 dated 2019-01-14 The results of the examination are contained in the above mentioned report and the relating documents mentioned within.

Certificate registration no.	515356 MRA
Certificate unique ID	170731526
Effective date	2019-01-14
Expiry date	2024-01-13
Frankfurt am Main	2019-01-14

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.

411.23 Version 1.0

Annex to certificate
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Certificate unique ID: 170731526
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Product:

Acclino® flex Stent
Acclino® flex Stent System

Acclino® flex plus Stent
Acclino® flex plus Stent System