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)

Accero® Stent and Accero® Stent System

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: Dossier DQS_1041-1-Accero_2014-11-20 dated 2014-11-20
Änderung Sterilisationsprozess dated 2016-06-14
Dossier DQS_1041-1-Accero_Optimization 20 dated 2018-06-29

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

Examination report: 1540_11d_Bericht_Produktprüfung_Accero+Rev.+2-final dated 2015-05-25
Bericht_Produktprüfung_Acandis-wg-Osypka_V1 dated 2016-07-11
411_18e_Report_TFR_Accero Rev. 3 dated 2018-07-30

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

Certificate registration no.	517166 MRA
Certificate unique ID	170719297
Effective date	2018-07-30
Expiry date	2020-05-24
Frankfurt am Main	2018-07-30

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.