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)

NeuroSpeed® PTA Balloon Catheter

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: NeuroSpeed dated 2014-03-25
Zusammenfassung TD NeuroSpeed 2015-10-19 dated 2015-10-19

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

Examination report: DE_370_1_3_Bericht_EGA_NeuroSpeed_V1 dated 2014-05-26
411_18d_Bericht_NeuroSpeed_V2 dated 2015-12-20

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

Certificate registration no.	516771 MRA
Certificate unique ID	170684767
Effective date	2017-06-29
Expiry date	2019-05-25
Frankfurt am Main	2017-06-29

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.