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)

Aperio® Recanalisation Device
Aperio® Thrombectomy Device
Aperio® Hybrid Thrombectomy Device

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_Aperio-E_A dated 24.10.2018
STED_CE-Approval_Aperio Hybrid-E_A.pdf dated 24.10.2018

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

Examination report: 411_18e_Report_TFR_Sample dated 28.02.2019
411_18e_Report_TFR_ Aperio Hybrid.docx dated 12.03.2019

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

Certificate registration no.	516327 MRA
Certificate unique ID	170738074
Effective date	2019-03-12
Expiry date	2024-02-27
Frankfurt am Main	2019-03-12

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.