



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

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: TD Aperio dated 2014-02-13
Änderung Sterilisationsprozess dated 2016-06-14

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

Examination report: DE_370_1_3_Bericht_EGA+Aperio_Rev-+1 dated 2014-04-17
Bericht_Produktprüfung_Acandis-wg-Osypka_V1 dated 2016-07-11

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	170684761
Effective date	2017-06-29
Expiry date	2019-04-16
Frankfurt am Main	2017-06-29

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

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