EC-CERTIFICATE

(Full quality assurance system)

This is to certify that the company

Acandis GmbH

Theodor-Fahrner-Strasse 6
75177 Pforzheim
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Catheter, Stents, Stent Delivery Systems and endovascular Medical Devices for neurological, cardiological and peripheral Applications according to Annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	516802 MR2
Certificate unique ID	170715679
Effective date	2018-11-12
Expiry date	2022-06-28
Frankfurt am Main	2018-11-12

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.

411.20 Version 1.0

Annex to certificate
Certificate registration No.: 516802 MR2
Certificate unique ID: 170715679
Effective date: 2018-11-12

Acandis GmbH

Theodor-Fahrner-Strasse 6
75177 Pforzheim
Germany

Device family	Device	Class	GMDN
Microcatheter	NeuroSlider®	III	10691
Embolisation Device/System	Derivo®	III	46352
	Derivo® mini	III	46352
Catheter	NeuroBridge®	III	17846
PTA Balloon Catheter	NeuroSpeed®	III	17184
Acclino® Stent	Acclino® flex Stent	III	46352
	Acclino® flex Stent System	III	46352
	Acclino® flex plus Stent	III	46352
	Acclino® flex plus Stent System	III	46352
	Acandis® BTK flex Stent	IIb	46352
	Acandis® BTK flex plus Stent	IIb	46352
Accero® Stent	Accero® Stent	III	46352
	Accero® Stent System	III	46352
Aperio® Recanalisation Device	Aperio® Thrombectomy Device	III	61779
Credo® Stent	Credo® Stent	III	46352

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

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.

acandis

Declaration of Conformity

according to directive 93/42/EEC

Product	**Accero® Stent and Accero® Stent System** Product listing see page 2
Class	**III** **Rule 8, according to directive 93/42/EEC annex IX**
UMDNS/GMDN-No.	**17-461/46352**
Manufacturer	**Acandis GmbH** **Theodor-Fahrner-Straße 6, 75177 Pforzheim** **Germany**
Manufacturing facility	**Acandis GmbH** **Theodor-Fahrner-Straße 6, 75177 Pforzheim** **Germany**

We hereby declare under our sole responsibility the conformity of the above mentioned products with the directive 93/42/EEC.

Notified body	DQS Medizinprodukte GmbH August-Schanz-Straße 21 60443 Frankfurt Germany notified body no. 0297
Selected conformity assessment procedure	directive 93/42/EEC annex II, section 3 & 4
QS Certificate	No. 516802 MR2 valid until 2022-06-28
EC Design Examination Certificate	No. 517166 MRA valid until 2020-05-24
Declaration of Conformity valid until	2019-07-29

Pforzheim, 2018-07-30

.....

Stefan Höfele
Director Regulatory Affairs

Declaration of Conformity Accero® Stent and Accero® Stent System

Product listing

Article number	Name	Size
01-000800	Accero® Stent	2.5 mm x 10 mm
01-000801	Accero® Stent	2.5 mm x 15 mm
01-000802	Accero® Stent	2.5 mm x 20 mm
01-000806	Accero® Stent	3.5 mm x 10 mm
01-000807	Accero® Stent	3.5 mm x 15 mm
01-000808	Accero® Stent	3.5 mm x 20 mm
01-000841	Accero® Stent	3.5 mm x 25 mm
01-000813	Accero® Stent	4.5 mm x 15 mm
01-000814	Accero® Stent	4.5 mm x 20 mm
01-000842	Accero® Stent	4.5 mm x 25 mm
01-000815	Accero® Stent System	2.5 mm x 10 mm
01-000816	Accero® Stent System	2.5 mm x 15 mm
01-000817	Accero® Stent System	2.5 mm x 20 mm
01-000821	Accero® Stent System	3.5 mm x 10 mm
01-000822	Accero® Stent System	3.5 mm x 15 mm
01-000823	Accero® Stent System	3.5 mm x 20 mm
01-000843	Accero® Stent System	3.5 mm x 25 mm
01-000828	Accero® Stent System	4.5 mm x 15 mm
01-000829	Accero® Stent System	4.5 mm x 20 mm
01-000844	Accero® Stent System	4.5 mm x 25 mm

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:

TD Acclino dated 2014-01-13
Amendment Shelf life Februar 2014
TD Acclino dated 2017-07-11
TD Acclino dated 2014-09-05 and 2014-09-17
TD Acclino, AC_DOSI_1013-5-D_C.pdf & AC_DOSI_1013-7-D_A.pdf dated 2015-01-26
Änderung Sterilisationsprozess dated 2016-06-14
TD Acclino flex plus Stents & System datet 2016-06-23
TD Acclino flex plus Stents & System, AC_DOSI_1013-7-D_B dated 2017-07-12 for Acclino® fle

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

Examination report:

DE_370_1_3_Bericht EGA Acclino_Rev.2.doc v. 26.02.2014
DE_370_1_3_Bericht_EGA Acclino_Rev 3 dated 2014-08-11
DE_370_1_3_Bericht_EGA+Acclino_Rev.+3 dated 2014-11-09
DE_370_1_3_Bericht_EGA+Acclino_Rev.+4 dated 2015-03-29
Bericht_Produktprüfung_Acandis-wg-Osypka_V1 dated 2016-07-11
DE_370_1_3_Bericht_EGA+Acclino_Rev.+5 dated 2016-07-17
DE_370_1_3_Bericht_EGA Acclino_Rev. 6 dated 2017-12-21

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	170700438
Effective date	2017-12-21
Expiry date	2019-02-03
Frankfurt am Main	2017-12-21

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.

411.23 Version 1.0

Annex to certificate
Certificate registration No.: 515356 MRA
Certificate unique ID: 170700438
Effective date: 2017-12-21

Acandis GmbH

Theodor-Fahrner-Strasse 6
75177 Pforzheim
Germany

Product:

Acclino® flex Stent
Acclino® flex Stent System

Acclino® flex plus Stent
Acclino® flex plus Stent System

acandis

Declaration of Conformity

according to directive 93/42/EEC

Product	**Acclino® flex plus Stent** Product listing see page 2
Class	**III** **Rule 8, according to directive 93/42/EEC annex IX**
UMDNS/GMDN-No.	**17-461/46352**
Manufacturer	**Acandis GmbH** **Theodor-Fahrner-Straße 6** **75177 Pforzheim** **Germany**
Manufacturing facility	**Acandis GmbH** **Theodor-Fahrner-Straße 6** **75177 Pforzheim** **Germany**

We hereby declare under our sole responsibility the conformity of the above mentioned products with the directive 93/42/EEC.

Notified body	DQS Medizinprodukte GmbH August-Schanz-Straße 21 60443 Frankfurt Germany notified body no. 0297
Selected conformity assessment procedure	directive 93/42/EEC annex II, section 3 & 4
QS Certificate	No. 516802 MR2 valid until 2022-06-28
EC Design Examination Certificate	No. 515356 MRA valid until 2019-02-03
Declaration of Conformity valid until	2018-12-27

Pforzheim, 2017-12-21

Stefan Höfele
Director Regulatory Affairs

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)

Derivo® Embolisation Device and Derivo® Embolisation System
Derivo® mini Embolisation Device/ Derivo® mini Embolisation 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: STED_CE-Approval_Derivo Embolisation Device-E_A dated 2018-06-22
STED_CE-Approval_Derivo mini Embolisation Device-E_A dated 2018-09-10

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

Examination report: 411_18e_Report_TFR_Derivo_V1 dated 2018-08-26
411_18e_Report_TFR_Derivo_V2 dated 2018-11-11

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

Certificate registration no.	513562 MRA
Certificate unique ID	170727178
Effective date	2018-11-12
Expiry date	2023-08-25
Frankfurt am Main	2018-11-12

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.

Declaration of Conformity

according to directive 93/42/EEC

Product	**Derivo® mini Embolisation Device & System** Product listing see page 2
Class	**III** **Rule 8, according to directive 93/42/EEC annex IX**
UMDNS/GMDN-No.	**17-461/46352**
Manufacturer	**Acandis GmbH** **Theodor-Fahrner-Straße 6** **75177 Pforzheim** **Germany**
Manufacturing facility	**Acandis GmbH** **Theodor-Fahrner-Straße 6** **75177 Pforzheim** **Germany**

We hereby declare under our sole responsibility the conformity of the above mentioned products with the directive 93/42/EEC.

Notified body	DQS Medizinprodukte GmbH August-Schanz-Straße 21 60443 Frankfurt Germany notified body no. 0297
Selected conformity assessment procedure	directive 93/42/EEC annex II, section 3 & 4
QS Certificate	No. 516802 MR2 valid until 2022-06-28
EC Design Examination Certificate	No. 513562 MRA valid until 2023-08-25
Declaration of Conformity valid until	2019-11-11

Pforzheim, 2018-11-12

.....

Stefan Höfele
Director Regulatory Affairs

Declaration of Conformity Derivo® mini Embolisation Device & System
Product listing

Aticle number	Name	Size
01-000416	Derivo mini Embolisation Device	3.5mm x 15mm
01-000417	Derivo mini Embolisation Device	3.5mm x 20mm
01-000418	Derivo mini Embolisation Device	3.5mm x 25mm
01-000420	Derivo mini Embolisation Device w/o tip	3.5mm x 20mm
01-000421	Derivo mini Embolisation Device w/o tip	3.5mm x 25mm
01-000422	Derivo mini Embolisation Device	3.0mm x 15mm
01-000423	Derivo mini Embolisation Device	3.0mm x 20mm
01-000424	Derivo mini Embolisation Device	3.0mm x 25mm
01-000426	Derivo mini Embolisation Device w/o tip	3.0mm x 20mm
01-000427	Derivo mini Embolisation Device w/o tip	3.0mm x 25mm
01-000428	Derivo mini Embolisation Device	2.5mm x 15mm
01-000429	Derivo mini Embolisation Device	2.5mm x 20mm
01-000430	Derivo mini Embolisation Device	2.5mm x 25mm
01-000432	Derivo mini Embolisation Device w/o tip	2.5mm x 20mm
01-000433	Derivo mini Embolisation Device w/o tip	2.5mm x 25mm
01-000434	Derivo mini Embolisation System	3.5mm x 15mm
01-000435	Derivo mini Embolisation System	3.5mm x 20mm
01-000436	Derivo mini Embolisation System	3.5mm x 25mm
01-000438	Derivo mini Embolisation System w/o tip	3.5mm x 20mm
01-000439	Derivo mini Embolisation System w/o tip	3.5mm x 25mm
01-000440	Derivo mini Embolisation System	3.0mm x 15mm
01-000441	Derivo mini Embolisation System	3.0mm x 20mm
01-000442	Derivo mini Embolisation System	3.0mm x 25mm
01-000444	Derivo mini Embolisation System w/o tip	3.0mm x 20mm
01-000445	Derivo mini Embolisation System w/o tip	3.0mm x 25mm
01-000446	Derivo mini Embolisation System	2.5mm x 15mm
01-000447	Derivo mini Embolisation System	2.5mm x 20mm
01-000448	Derivo mini Embolisation System	2.5mm x 25mm
01-000450	Derivo mini Embolisation System w/o tip	2.5mm x 20mm
01-000451	Derivo mini Embolisation Device w/o tip	2.5mm x 25mm

acandis

Declaration of Conformity

according to directive 93/42/EEC

Product	**Derivo® Embolisation Device & System** Product listing see page 2 et seqq.
Class	**III** **Rule 8, according to directive 93/42/EEC annex IX**
UMDNS/GMDN-No.	**17-461/46352**
Manufacturer	**Acandis GmbH** **Theodor-Fahrner-Straße 6** **75177 Pforzheim** **Germany**
Manufacturing facility	**Acandis GmbH** **Theodor-Fahrner-Straße 6** **75177 Pforzheim** **Germany**

We hereby declare under our sole responsibility the conformity of the above mentioned products with the directive 93/42/EEC.

Notified body	DQS Medizinprodukte GmbH August-Schanz-Straße 21 60443 Frankfurt Germany notified body no. 0297
Selected conformity assessment procedure	directive 93/42/EEC annex II, section 3 & 4
QS Certificate	No. 516802 MR2 valid until 2022-06-28
EC Design Examination Certificate	No. 513562 MRA valid until 2023-08-25
Declaration of Conformity valid until	2019-11-11

Pforzheim, 2018-11-12

.....

Stefan Höfele
Director Regulatory Affairs

Declaration of Conformity Derivo® Embolisation Device & System

Product listing

Aticle number	Name	Size
01-000300	Derivo Embolisation System	4.0mm x 20mm
01-000301	Derivo Embolisation System	4.5mm x 20mm
01-000302	Derivo Embolisation System	5.0mm x 20mm
01-000303	Derivo Embolisation System	5.5mm x 20mm
01-000304	Derivo Embolisation System	6.0mm x 20mm
01-000305	Derivo Embolisation System	4.0mm x 25mm
01-000306	Derivo Embolisation System	4.5mm x 25mm
01-000307	Derivo Embolisation System	5.0mm x 25mm
01-000308	Derivo Embolisation System	5.5mm x 25mm
01-000309	Derivo Embolisation System	6.0mm x 25mm
01-000310	Derivo Embolisation System	4.0mm x 30mm
01-000311	Derivo Embolisation System	4.5mm x 30mm
01-000312	Derivo Embolisation System	5.0mm x 30mm
01-000313	Derivo Embolisation System	5.5mm x 30mm
01-000314	Derivo Embolisation System	6.0mm x 30mm
01-000315	Derivo Embolisation System w/o Tip	4.0mm x 20mm
01-000316	Derivo Embolisation System w/o Tip	4.5mm x 20mm
01-000317	Derivo Embolisation System w/o Tip	5.0mm x 20mm
01-000318	Derivo Embolisation System w/o Tip	5.5mm x 20mm
01-000319	Derivo Embolisation System w/o Tip	6.0mm x 20mm
01-000320	Derivo Embolisation System w/o Tip	4.0mm x 25mm
01-000321	Derivo Embolisation System w/o Tip	4.5mm x 25mm
01-000322	Derivo Embolisation System w/o Tip	5.0mm x 25mm
01-000323	Derivo Embolisation System w/o Tip	5.5mm x 25mm
01-000324	Derivo Embolisation System w/o Tip	6.0mm x 25mm
01-000325	Derivo Embolisation System w/o Tip	4.0mm x 30mm
01-000326	Derivo Embolisation System w/o Tip	4.5mm x 30mm
01-000327	Derivo Embolisation System w/o Tip	5.0mm x 30mm
01-000328	Derivo Embolisation System w/o Tip	5.5mm x 30mm
01-000329	Derivo Embolisation System w/o Tip	6.0mm x 30mm

Aticle number	Name	Size
01-000330	Derivo Embolisation Device	4.0mm x 20mm
01-000331	Derivo Embolisation Device	4.5mm x 20mm
01-000332	Derivo Embolisation Device	5.0mm x 20mm
01-000333	Derivo Embolisation Device	5.5mm x 20mm
01-000334	Derivo Embolisation Device	6.0mm x 20mm
01-000335	Derivo Embolisation Device	4.0mm x 25mm
01-000336	Derivo Embolisation Device	4.5mm x 25mm
01-000337	Derivo Embolisation Device	5.0mm x 25mm
01-000338	Derivo Embolisation Device	5.5mm x 25mm
01-000339	Derivo Embolisation Device	6.0mm x 25mm
01-000340	Derivo Embolisation Device	4.0mm x 30mm
01-000341	Derivo Embolisation Device	4.5mm x 30mm
01-000342	Derivo Embolisation Device	5.0mm x 30mm
01-000343	Derivo Embolisation Device	5.5mm x 30mm
01-000344	Derivo Embolisation Device	6.0mm x 30mm
01-000345	Derivo Embolisation Device w/o Tip	4.0mm x 20mm
01-000346	Derivo Embolisation Device w/o Tip	4.5mm x 20mm
01-000347	Derivo Embolisation Device w/o Tip	5.0mm x 20mm
01-000348	Derivo Embolisation Device w/o Tip	5.5mm x 20mm
01-000349	Derivo Embolisation Device w/o Tip	6.0mm x 20mm
01-000350	Derivo Embolisation Device w/o Tip	4.0mm x 25mm
01-000351	Derivo Embolisation Device w/o Tip	4.5mm x 25mm
01-000353	Derivo Embolisation Device w/o Tip	5.5mm x 25mm
01-000354	Derivo Embolisation Device w/o Tip	6.0mm x 25mm
01-000355	Derivo Embolisation Device w/o Tip	4.0mm x 30mm
01-000356	Derivo Embolisation Device w/o Tip	4.5mm x 30mm
01-000357	Derivo Embolisation Device w/o Tip	5.0mm x 30mm
01-000358	Derivo Embolisation Device w/o Tip	5.5mm x 30mm
01-000359	Derivo Embolisation Device w/o Tip	6.0mm x 30mm
01-000352	Derivo Embolisation Device w/o Tip	5.0mm x 25mm
01-000360	Derivo Embolisation Device w/o Tip	4.0mm x 40mm
01-000361	Derivo Embolisation Device w/o Tip	4.5mm x 40mm

Aticle number	Name	Size
01-000362	Derivo Embolisation Device w/o Tip	5.0mm x 40mm
01-000363	Derivo Embolisation Device w/o Tip	5.0mm x 50mm
01-000364	Derivo Embolisation Device w/o Tip	5.5mm x 40mm
01-000365	Derivo Embolisation Device w/o Tip	5.5mm x 50mm
01-000366	Derivo Embolisation Device w/o Tip	6.0mm x 40mm
01-000367	Derivo Embolisation Device w/o Tip	6.0mm x 50mm
01-000368	Derivo Embolisation System w/o Tip	4.0mm x 40mm
01-000369	Derivo Embolisation System w/o Tip	4.5mm x 40mm
01-000370	Derivo Embolisation System w/o Tip	5.0mm x 40mm
01-000371	Derivo Embolisation System w/o Tip	5.0mm x 50mm
01-000372	Derivo Embolisation System w/o Tip	5.5mm x 40mm
01-000373	Derivo Embolisation System w/o Tip	5.5mm x 50mm
01-000374	Derivo Embolisation System w/o Tip	6.0mm x 40mm
01-000375	Derivo Embolisation System w/o Tip	6.0mm x 50mm
01-000376	Derivo Embolisation System	4.0mm x 15mm
01-000377	Derivo Embolisation System	4.5mm x 15mm
01-000378	Derivo Embolisation System	5.0mm x 15mm
01-000379	Derivo Embolisation System	5.5mm x 15mm
01-000380	Derivo Embolisation System	6.0mm x 15mm
01-000381	Derivo Embolisation Device	4.0mm x 15mm
01-000382	Derivo Embolisation Device	4.5mm x 15mm
01-000383	Derivo Embolisation Device	5.0mm x 15mm
01-000384	Derivo Embolisation Device	5.5mm x 15mm
01-000385	Derivo Embolisation Device	6.0mm x 15mm
01-000400	Derivo Embolisation System	3.5mm x 15mm
01-000401	Derivo Embolisation System	3.5mm x 20mm
01-000402	Derivo Embolisation System	3.5mm x 25mm
01-000403	Derivo Embolisation System	3.5mm x 30mm
01-000404	Derivo Embolisation System w/o Tip	3.5mm x 20mm
01-000405	Derivo Embolisation System w/o Tip	3.5mm x 25mm
01-000406	Derivo Embolisation System w/o Tip	3.5mm x 30mm
01-000407	Derivo Embolisation System w/o Tip	3.5mm x 40mm

Aticle number	Name	Size
01-000408	Derivo Embolisation Device	3.5mm x 15mm
01-000409	Derivo Embolisation Device	3.5mm x 20mm
01-000410	Derivo Embolisation Device	3.5mm x 25mm
01-000411	Derivo Embolisation Device	3.5mm x 30mm
01-000412	Derivo Embolisation Device w/o Tip	3.5mm x 20mm
01-000413	Derivo Embolisation Device w/o Tip	3.5mm x 25mm
01-000414	Derivo Embolisation Device w/o Tip	3.5mm x 30mm
01-000415	Derivo Embolisation Device w/o Tip	3.5mm x 40mm

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.

Declaration of Conformity

according to directive 93/42/EEC

Product	**Aperio® Thrombectomy Devices** Product listing see page 2
Class	**III** **Rule 7, bullet point 2,** **according to directive 93/42/EEC annex IX**
UMDNS/GMDN-No.	**17-461/61779**
Manufacturer	**Acandis GmbH** **Theodor-Fahrner-Straße 6** **75177 Pforzheim** **Germany**
Manufacturing facility	**Acandis GmbH** **Theodor-Fahrner-Straße 6** **75177 Pforzheim** **Germany**

We hereby declare under our sole responsibility the conformity of the above mentioned products with the directive 93/42/EEC.

Notified body	DQS Medizinprodukte GmbH August-Schanz-Straße 21 60443 Frankfurt Germany notified body no. 0297
Selected conformity assessment procedure	directive 93/42/EEC annex II, section 3 & 4
QS Certificate	No. 516802 MR2 valid until 2022-06-28
EC Design Examination Certificate	No. 516327 MRA valid until 2019-04-16
Declaration of Conformity valid until	2019-07-05

Pforzheim, 2018-07-06

.....

Stefan Höfele,
Director Regulatory Affairs

Declaration of Conformity Aperio® Thrombectomy Device

Product listing

Article number	Name	Size
01-000700	Aperio® Thrombectomy Device	3.5mm x 28mm
01-000701	Aperio® Thrombectomy Device	4.5mm x 30mm
01-000702	Aperio® Thrombectomy Device	4.5mm x 40mm
01-000703	Aperio® Thrombectomy Device	6.0mm x 40mm

EC Design Examination Certificate

Council Directive 93/42/EEC Annex II Section 4

This is to certify that the manufacturer

Acandis GmbH

Theodor-Fahrner-Str. 6
75177 Pforzheim
Germany

that the design of the following device(s)

NeuroSlider® Microcatheter

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. 376850 MR2. Changes to the approved design are subject to further approval by the Notified Body.

Basis of examination: Produktakte B Zusammenfassung TD NeuroSlider 2018-02-07

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

Examination report: 411_18d_Bericht_NeuroSlider_V1 dated 2018-03-16

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

Certificate registration no.	376850 MRA
Certificate unique ID	170710589
Effective date	2018-03-16
Expiry date	2023-03-15
Frankfurt am Main	2018-03-16

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.

Declaration of Conformity

according to directive 93/42/EEC

Product	**NeuroSlider® Microcatheter** Product listing see page 2
Class	**III** **Rule 7, bullet point 2,** **according to directive 93/42/EEC annex IX**
UMDNS/GMDN-No.	**17-846/10691**
Manufacturer	**Acandis GmbH** **Theodor-Fahrner-Straße 6** **75177 Pforzheim** **Germany**
Manufacturing facility	**Acandis GmbH** **Theodor-Fahrner-Straße 6** **75177 Pforzheim** **Germany**

We hereby declare under our sole responsibility the conformity of the above mentioned products with the directive 93/42/EEC.

Notified body	DQS Medizinprodukte GmbH August-Schanz-Straße 2 60433 Frankfurt am Main Germany notified body no. 0297
Selected conformity assessment procedure	directive 93/42/EEC annex II, section 3 & 4
QS Certificate	No. 516802 MR2 valid until 2022-06-28
EC Design Examination Certificate	No. 376850 MRA valid until 2023-03-15
Declaration of Conformity valid until	2019-03-15

Pforzheim, 2018-03-16

.....

Stefan Höfele
Director Regulatory Affairs

Declaration of Conformity NeuroSlider® Microcatheter

Product listing

Article number	Name	Size (inside diameter)
01-000272	NeuroSlider® 17	0,0165"
01-000273	NeuroSlider® 21	0,021"
01-000274	NeuroSlider® 27	0,027"

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)

NeuroBridge® 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:	STED_CE-Approval_NeuroBridge Catheter-E_A dated 2018-05-30 Further basis for the examination is referenced in the examination report and relating documents mentioned below.
Examination report:	411_18e_Report_TFR_euroBridge_V1 dated 2018-08-29 The results of the examination are contained in the above mentioned report and the relating documents mentioned within.

Certificate registration no.	513725 MRA
Certificate unique ID	170721330
Effective date	2018-11-03
Expiry date	2023-11-02
Frankfurt am Main	2018-08-29

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.

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 Zusammenfassung TD NeuroSpeed 2018-05-18 dated 2018-05-18 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 2015-12-20 411_18d_Bericht_NeuroSpeed dated 2018-10-25 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	170725921
Effective date	2018-10-25
Expiry date	2019-05-25
Frankfurt am Main	2018-10-25

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.

Declaration of Conformity

according to directive 93/42/EEC

Product	**NeuroSpeed® PTA Balloon Catheter** Product listing see page 2
Class	**III** **Rule 7,** **bullet point 2,** **according to directive 93/42/EEC annex IX**
UMDNS/GMDN-No.	**17-184/17184**
Manufacturer	**Acandis GmbH** **Theodor-Fahrner-Straße 6** **75177 Pforzheim** **Germany**
Manufacturing facility	**Acandis GmbH** **Theodor-Fahrner-Straße 6** **75177 Pforzheim** **Germany**

We hereby declare under our sole responsibility the conformity of the above mentioned products with the directive 93/42/EEC.

Notified body	DQS Medizinprodukte GmbH August-Schanz-Straße 2 60433 Frankfurt am Main Germany notified body no. 0297
Selected conformity assessment procedure	directive 93/42/EEC annex II, section 3 & 4
QS Certificate	No. 516802 MR2 valid until 2022-06-28
EC Design Examination Certificate	No. 516771 MRA valid until 2019-05-25
Declaration of Conformity valid until	2019-10-24

Pforzheim, 2018-10-25

.....

Stefan Höfele
Director Regulatory Affairs

Declaration of Conformity NeuroSpeed® PTA Balloon Catheter

Product listing

Article number	Name	Size
01-000600	NeuroSpeed® PTA Balloon Catheter	2.0mm x 8mm
01-000601	NeuroSpeed® PTA Balloon Catheter	2.5mm x 8mm
01-000602	NeuroSpeed® PTA Balloon Catheter	3.0mm x 8mm
01-000603	NeuroSpeed® PTA Balloon Catheter	3.5mm x 8mm
01-000604	NeuroSpeed® PTA Balloon Catheter	4.0mm x 8mm
01-000605	NeuroSpeed® PTA Balloon Catheter	1.5mm x 8mm