TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chișinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com> <tehnomedicamd@gmail.com>

Anexa nr. 7
la Documentația standard nr.115
din 15.09.2021

CERERE DE PARTICIPARE

Către **Centrul pentru Achiziții Publice Centralizate în Sănătate**

Stimaţi domni,

Ca urmare a anunțului/invitației de participare/de preselecție apărut în Buletinul achizițiilor publice și/sau Jurnalul Oficial al Uniunii Europene, nr. *ocds-b3wdp1-MD-1637327903323, ID:21047181 din 21.12.2021* privind aplicarea procedurii pentru atribuirea contractului privind *achiziționarea consumabilelor costisitoare pentru cabinetul de cardiologie intervențională, conform necesităților IMSP Spitalul Clinic Republican „ Timofei Moșneaga” și IMSP Institutul Neurologie și Neurochirurgie pentru anul 2022*, noi, *Tehnomedica SRL,* am luat cunoștință de condițiile și de cerințele expuse în documentația de atribuire și exprimăm prin prezenta interesul de a participa, în calitate de ofertant/candidat, neavînd obiecții la documentația de atribuire.

Data completării: 20.12.2021

Cu stimă,

Tehnomedica SRL

Director Tatiana Roibu

(semnătura autorizată)

TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chișinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com> <tehnomedicamd@gmail.com>

Anexa nr. 8
la Documentația standard nr.115
din 15.09.2021

DECLARAŢIE
privind valabilitatea ofertei

Către **Centrul pentru Achiziții Publice Centralizate în Sănătate**

Stimaţi domni,

Ne angajăm să menținem oferta valabilă, privind *achiziționarea consumabilelor costisitoare pentru cabinetul de cardiologie intervențională, conform necesităților IMSP Spitalul Clinic Republican „Timofei Moșneaga” și IMSP Institutul Neurologie și Neurochirurgie pentru anul 2022* prin procedura de achiziție licitație deschisă, pentru o durată de 160 zile, (una sută șaizeci zile), respectiv până la data de 30.05.2022 (ziua/luna/anul), și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării: 21.12.2021

Cu stimă,

Tehnomedica SRL

Director Tatiana Roibu

(semnătura autorizată)

F/COM/CC/23/02

Nr. CIF26-842.2020
Data: 13 Februarie 2020

CERTIFICAT
PRIVIND EXISTENTA CONTURILOR CURENTE

Prin prezentul, **Mobiasbanca - OTP Group S.A.**, codul băncii (BIC): **MOBBMD22**, confirmă că compania **TEHNOMEDICA S.R.L.** cod fiscal (IDNO) **1002600053256**, detine următoarele conturi curente la Mobiasbanca - OTP Group S.A., Sucursala. 26 Negruzzi:

1. **MDL - MD65MO2224ASV98310887100**
2. **EUR - MD06MO2224ASV98311097100**

L.Ş.

Numele, Prenumele si Semnătura
Director sucursalei „Gheorghe Mocanu"

Executor :Eduard Cilcic
Tel: 022-812-150

Mobiasbanca - OTP Group S.A. • Capital Social: 100 000 000 MDL • Număr de înregistrare de stat – 1002600006089
bd. Ştefan cel Mare şi Sfînt 81A • MD-2012 Chişinău, Moldova • telefon: +373 22 256 456 • e-mail: info@mobiasbanca.md • www.mobiasbanca.md

REPUBLICA MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "TEHNOMEDICA"

ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT

Numărul de indentificare de stat - codul fiscal

1002600053256

Data înregistrării **17.04.2002**

Data eliberării **16.02.2005**

Bolboceanu Adela, registrator de stat
Funcția, numele, prenumele persoanei care a eliberat certificatul

semnătura

CAMERA ÎNREGISTRĂRII DE STAT 109 L.Ș.

MD 0027040

LISTA FONDATORILOR

SRL „TEHNOMEDICA”

Fondator unic: Roibu Tatiana

IDNP: 0992606484592

Nr. de contact: +37369909500

Anexa nr.7.2 la Instrucțiunea
aprobată prin ordinul IFPS
nr. 400 din 14 martie 2014

CC 04 AE

CERTIFICAT
privind lipsa sau existența restanțelor față de bugetul public național

Nr. / № A2121180 **din** / от 09.12.2021

1. Destinația / Назначение

PENTRU PARTICIPARE LA PROCEDURI DE ACHIZIȚII PUBLICE

2. Date despre contribuabil / Информация о налогоплательщике

Denumirea / Наименование	**Codul fiscal / Numărul de identificare** / Фискальный код / Идентификационный номер
TEHNOMEDICA S.R.L.	1002600053256
Adresa sediului de bază (strada, numărul) / Адрес основного месторасположения (улица, номер)	**Codul - Denumirea localității** / Код - Наименование населенного пункта
Ciuflea nr.38 bl.1	0130-SEC.CENTRU

3. Atestarea lipsei sau existenței restanțelor conform datelor Sistemului Informațional Automatizat / Подтверждение отсутствия или наличия недоимки согласно данных Информационной автоматизированной системы

La data emiterii prezentului certificat restanța față de bugetul public național constituie/ На дату выдачи данной справки недоимка перед национальным публичным бюджетом составляет: **0,00** lei/лей.

4. Valabil pînă la / Действителен до 24.12.2021

5. Autentificarea Serviciului Fiscal de Stat / Подтверждение Государственной налоговой службы

Șef DDF Centru — **Funcția**/Должность

Semnătura/Подпись

Albina IȘCOVA — **Numele și prenumele**/Фамилия и имя

L.Ș/ М.П.

Executor: Gavajuc V. — **Numele și prenumele**/Фамилия и имя

Este extras din Sistemul Informațional al SFS SIA „Contul curent al contribuabilului"// 09.12.2021 ora 8:51:46
cu aplicarea prevederilor pct. 82-83 Ordin IFPS nr.400 din 14.03.2014 (Monitorul Oficial 72-77/399, 28.03.2014)

NOTA (0,00)

Data prezentării 21.04.2021 14:23:33

Anexe la SNC
"Prezentarea situatiilor financiare"
Aprobat de Ministerul Finantelor
al Republicii Moldova

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2020 - 31.12.2020

Entitatea: TEHNOMEDICA S.R.L.
Cod CUIÎO: 37700778
Cod IDNO: 1002600053256

Sediul:
MD: 2001
Raionul(municipiul): 102, DDF CENTRU
Cod CUATM: 0130, SEC.CENTRU
Strada: SECTORUL CENTRAL STR.Ciuflea nr.38 bl.1

Activitatea principală: G4646, Comert cu ridicata al produselor farmaceutice
Forma de proprietate: 16, Proprietate colectivă
Forma organizatorico-juridică: 530, Societăți cu răspundere limitată

Date de contact:
Telefon: +37369153407
WEB:
E-mail: ecaterin.popescu@gmail.com
Numele și coordonatele al contabilului-șef: Dl (dna) Popescu Ecaterina Tel. 022601102

Numărul mediu al salariaților în perioada de gestiune: 5 **persoane.**

Persoanele responsabile de semnarea situațiilor financiare* Roibu Tatiana

Unitatea de măsură: leu

BILANȚUL

Anexa 1

la

Nr. cpt.	Indicatori	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfîrșitul perioadei de gestiune
1	2	3	4	5
	A C T I V			
	ACTIVE IMOBILIZATE **I. Imobilizări necorporale**			
	1. Imobilizări necorporale în curs de execuție	010		
	2. Imobilizări necorporale în exploatare, total	020	407	319
	din care: 2.1. concesiuni, licențe și mărci	021		
	2.2. drepturi de autor și titluri de protecție	022		
	2.3. programe informatice	023		
	2.4. alte imobilizări necorporale	024	407	319
	3. Fond comercial	030		
	4. Avansuri acordate pentru imobilizări necorporale	040	1404169	2861138
	Total imobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040)	050	1404576	2861457
	II. Imobilizări corporale			
	1. Imobilizări corporale în curs de execuție	060		
	2. Terenuri	070		
	3. Mijloace fixe, total	080	2364772	2174915
	din care: 3.1. clădiri	081	1147126	1038156
	3.2. construcții speciale	082		
	3.3. mașini, utilaje și instalații tehnice	083	28036	34609
	3.4. mijloace de transport	084	1128114	1042950

A.	3.5. inventar și mobilier	085		
	3.6. alte mijloace fixe	086	61496	59200
	4. Resurse minerale	090		
	5. Active biologice imobilizate	100		
	6. Investiții imobiliare	110		
	7. Avansuri acordate pentru imobilizări corporale	120		
	Total imobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	2364772	2174915
	III. Investiții financiare pe termen lung			
	1. Investiții financiare pe termen lung în părți neafiliate	140		
	2. Investiții financiare pe termen lung în părți afiliate, total	150		
	din care: 2.1. acțiuni și cote de participație deținute în părțile afiliate	151		
	2.2 împrumuturi acordate părților afiliate	152		
	2.3 împrumuturi acordate aferente intereselor de participare	153		
	2.4 alte investiții financiare	154		
	Total investiții financiare pe termen lung (rd.140 + rd.150)	160		
	IV. Creanțe pe termen lung și alte active imobilizate			
	1. Creanțe comerciale pe termen lung	170		
	2. Creanțe ale părților afiliate pe termen lung	180		
	inclusiv: creanțe aferente intereselor de participare	181		
	3. Alte creanțe pe termen lung	190		
	4. Cheltuieli anticipate pe termen lung	200		
	5. Alte active imobilizate	210		
	Total creanțe pe termen lung și alte active imobilizate (rd.170 + rd.180 + rd.190 + rd.200 + rd.210)	220		
	TOTAL ACTIVE IMOBILIZATE (rd.050 + rd.130 + rd.160 + rd.220)	230	3769348	5036372
B.	**ACTIVE CIRCULANTE** **I. Stocuri**			
	1. Materiale și obiecte de mică valoare și scurtă durată	240	31417	4996
	2. Active biologice circulante	250		
	3. Producția în curs de execuție	260		
	4. Produse și mărfuri	270	1242672	1326025
	5. Avansuri acordate pentru stocuri	280		
	Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	1274089	1331021
	II. Creanțe curente și alte active circulante			
	1. Creanțe comerciale curente	300	1090879	1022910
	2. Creanțe ale părților afiliate curente	310		
	inclusiv: creanțe aferente intereselor de participare	311		
	3. Creanțe ale bugetului	320	48364	6546
	4. Creanțele ale personalului	330		
	5. Alte creanțe curente	340	838	
	6. Cheltuieli anticipate curente	350	5421	13569
	7. Alte active circulante	360	63104	31297
	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	1208606	1074322
	III. Investiții financiare curente			
	1. Investiții financiare curente în părți neafiliate	380	150000	700000
	2. Investiții financiare curente în părți afiliate, total	390		
	din care: 2.1. acțiuni și cote de participație deținute în părțile afiliate	391		
	2.2. împrumuturi acordate părților afiliate	392		
	2.3. împrumuturi acordate aferente intereselor de participare	393		

	2.4. alte investiții financiare în părți afiliate	394		
	Total investiții financiare curente (rd.380 + rd.390)	400	150000	700000
	IV. Numerar și documente bănești	410	8666885	6916759
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	11299580	10022102
	TOTAL ACTIVE (rd.230 + rd.420)	430	15068928	15058474
	P A S I V			
C.	**CAPITAL PROPRIU** **I. Capital social și neînregistrat**			
	1. Capital social	440	5400	5400
	2. Capital nevărsat	450	( )	( )
	3. Capital neînregistrat	460		
	4. Capital retras	470	( )	( )
	5. Patrimoniul primit de la stat cu drept de proprietate	480		
	Total capital social și neînregistrat (rd.440 + rd.450 + rd.460 + rd.470 + rd.480)	490	5400	5400
	II. Prime de capital	500		
	III. Rezerve			
	1. Capital de rezervă	510		
	2. Rezerve statutare	520		
	3. Alte rezerve	530		
	Total rezerve (rd.510 + rd.520 + rd.530)	540		
	IV. Profit (pierdere)			
	1. Corecții ale rezultatelor anilor precedenți	550	X	
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	560	14214199	12018454
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	2687032
	4. Profit utilizat al perioadei de gestiune	580	X	( )
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	14214199	14705486
	V. Rezerve din reevaluare	600		
	VI. Alte elemente de capital propriu	610		
	TOTAL CAPITAL PROPRIU (rd.490 + rd.500 + rd.540 + rd.590 + rd.600 + rd.610)	620	14219599	14710886
D.	**DATORII PE TERMEN LUNG**			
	1. Credite bancare pe termen lung	630		
	2. Împrumuturi pe termen lung	640		
	din care: 2.1. împrumuturi din emisiunea de obligațiuni	641		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	642		
	2.2. alte împrumuturi pe termen lung	643		
	3. Datorii comerciale pe termen lung	650		
	4. Datorii față de părțile afiliate pe termen lung	660		
	inclusiv: datorii aferente intereselor de participare	661		
	5. Avansuri primite pe termen lung	670		
	6. Venituri anticipate pe termen lung	680		
	7. Alte datorii pe termen lung	690		
	TOTAL DATORII PE TERMEN LUNG (rd.630 + rd.640 + rd.650 + rd.660 + rd.670 + rd.680 + rd.690)	700		
	DATORII CURENTE			
	1. Credite bancare pe termen scurt	710		
	2. Împrumuturi pe termen scurt, total	720		

E.	din care: 2.1. împrumuturi din emisiunea de obligațiuni	721		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	722		
	2.2. alte împrumuturi pe termen scurt	723		
	3. Datorii comerciale curente	730	275321	149510
	4. Datorii față de părțile afiliate curente	740		
	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	249170	
	6. Datorii față de personal	760		977
	7. Datorii privind asigurările sociale și medicale	770		
	8. Datorii față de buget	780	324838	197101
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
	11. Alte datorii curente	810		
	TOTAL DATORII CURENTE (rd.710 + rd.720 + rd.730 + rd.740 + rd.750 + rd.760 + rd.770 + rd.780 + rd.790 + rd.800 + rd.810)	820	849329	347588
F.	**PROVIZIOANE**			
	1. Provizioane pentru beneficiile angajaților	830		
	2. Provizioane pentru garanții acordate cumpărătorilor/clienților	840		
	3. Provizioane pentru impozite	850		
	4. Alte provizioane	860		
	TOTAL PROVIZIOANE (rd.830 + rd.840 + rd.850 + rd.860)	870		
	TOTAL PASIVE (rd.620 + rd.700 + rd.820 + rd.870)	880	15068928	15058474

SITUAȚIA DE PROFIT ȘI PIERDERE

de la 01.01.2020 pînă la 31.12.2020

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune	
		precedenta	curenta
1	2	3	4
Venituri din vînzări, total	010	21436657	16620028
din care: veniturи din vînzarea produselor și mărfurilor	011	17775775	13778008
veniturи din prestarea serviciilor și executarea lucrărilor	012	3660882	2842020
veniturи din contracte de construcție	013		
veniturи din contracte de leasing	014		
veniturи din contracte de microfinanțare	015		
alte venituri din vînzări	016		
Costul vînzărilor, total	020	15063379	12527753
din care: valoarea contabilă a produselor și mărfurilor vîndute	021	15063379	11595535
costul serviciilor prestate și lucrărilor executate terților	022		932218
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanțare	025		
alte costuri aferente vînzărilor	026		
Profit brut (pierdere brută) (rd.010 - rd.020)	030	6373278	4092275
Alte venituri din activitatea operațională	040	41518	986
Cheltuieli de distribuire	050	8704	
Cheltuieli administrative	060	2164450	1569273
Alte cheltuieli din activitatea operațională	070		17430
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	4241642	2506558

Venituri financiare, total	090	741192	1257613
din care: venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobînzi	093		
inclusiv: veniturile obținute de la părțile afiliate	094		
venituri din alte investiții financiare pe termen lung	095		
inclusiv: veniturile obținute de la părțile afiliate	096		
venituri aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	097		
venituri din ieșirea investițiilor financiare	098		
venituri aferente diferențelor de curs valutar și de sumă	099	741192	1257613
Cheltuieli financiare, total	100	680243	666851
din care: cheltuieli privind dobînzile	101		
inclusiv: cheltuielile aferente părților afiliate	102		
cheltuieli aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	103		
cheltuieli aferente ieșirii investițiilor financiare	104		
cheltuieli aferente diferențelor de curs valutar și de sumă	105	680243	666851
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	60949	590762
Venituri cu active imobilizate și excepționale	120		
Cheltuieli cu active imobilizate și excepționale	130		
Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere) (rd.120 - rd.130)	140		
Rezultatul din alte activități: profit (pierdere) (rd.110 + rd.140)	150	60949	590762
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	4302591	3097320
Cheltuieli privind impozitul pe venit	170	569409	410288
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	3733182	2687032

SITUAŢIA MODIFICĂRILOR CAPITALULUI PROPRIU

de la 01.01.2020 pînă la 31.12.2020

Anexa 3

Nr. d/o	Indicatori	Cod rd	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfîrșitul perioadei de gestiune
1	2	3	4	5	6	7
I.	**Capital social și neînregistrat**					
	1. Capital social	010	5400			5400
	2. Capital nevărsat	020	( )	( )	( )	( )
	3. Capital neînregistrat	030				
	4. Capital retras	040	( )	( )	( )	( )
	5. Patrimoniul primit de la stat cu drept de proprietate	050				
	Total capital social și neînregistrat (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060	5400			5400
II.	**Prime de capital**	070				
III.	**Rezerve**					
	1. Capital de rezervă	080				
	2. Rezerve statutare	090				
	3. Alte rezerve	100				
	Total rezerve (rd.080 + rd.090 + rd.100)	110				
	Profit (pierdere)					
	1. Corecții ale rezultatelor anilor precedenți	120	X			

IV.	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	130	14214199		2195745	12018454
	3. Profit net (pierdere netă) al perioadei de gestiune	140	X	2687032		2687032
	4. Profit utilizat al perioadei de gestiune	150	X	( )	( )	( )
	Total profit (pierdere) (rd.120 + rd.130 + rd.140 + rd.150)	160	14214199	2687032	2195745	14705486
V.	**Rezerve din reevaluare**	170				
VI.	**Alte elemente de capital propriu**	180				
	Total capital propriu (rd.060 + rd.070 + rd.110 + rd.160 + rd.170 + rd.180)	190	14219599	2687032	2195745	14710886

SITUAŢIA FLUXURILOR DE NUMERAR

de la 01.01.2020 pînă la 31.12.2020

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vînzări	010	24785768	17211991
Plăți pentru stocuri și servicii procurate	020	14966422	13370873
Plăți către angajați și organe de asigurare socială și medicală	030	596384	554000
Dobînzi plătite	040		
Plata impozitului pe venit	050	408570	414542
Alte încasări	060	1459997	2220519
Alte plăți	070	4278234	5025576
Fluxul net de numerar din activitatea operațională (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070)	080	5996155	67519
Fluxuri de numerar din activitatea de investiții			
Încasări din vînzarea activelor imobilizate	090		
Plăți aferente intrărilor de active imobilizate	100		
Dobînzi încasate	110		
Dividende încasate	120		
inclusiv: dividende încasate din străinătate	121		
Alte încasări (plăți)	130		
Fluxul net de numerar din activitatea de investiții (rd.090 - rd.100 + rd.110 + rd.120 ± rd.130)	140		
Fluxuri de numerar din activitatea financiară			
Încasări sub formă de credite și împrumuturi	150	992852	630000
Plăți aferente rambursării creditelor și împrumuturilor	160	330000	830000
Dividende plătite	170	1968000	2019064
inclusiv: dividende plătite nerezidenților	171		
Încasări din operațiuni de capital	180		
Alte încasări (plăți)	190		
Fluxul net de numerar din activitatea financiară (rd.150 - rd.160 - rd.170 + rd.180 ± rd.190)	200	-1305148	-2219064
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210	4691007	-2151545
Diferențe de curs valutar favorabile (nefavorabile)	220	-80398	401419
Sold de numerar la începutul perioadei de gestiune	230	4056276	8666885
Sold de numerar la sfîrșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240	8666885	6916759

Documente atașate - Notă explicativă (fișierul pdf)

Versiune de imprimare
Salvare

Recipisa

Respondent
Codul fiscal: 1002600053256, denumire: TEHNOMEDICA S.R.L.
A prezentat raportul: RSF1_21
Pentru perioada fiscala: A/2020
Data prezentarii: 21.04.2021
Marca temporală a raportului înregistrat în Sistemul de Raportare Electronică și expediat pentru procesare în Sistemul Informațional al BNS : 21.04.2021 14:23:33

Versiune de imprimare
Salvare

Recipisa 2

Respondent
Codul fiscal: 1002600053256, denumire: TEHNOMEDICA S.R.L.
A prezentat raportul: RSF1_21
Pentru perioada fiscala: A/2020
Data prezentarii: 21.04.2021
Marca temporală a raportului înregistrat în Sistemul Informațional al BNS : 21.04.2021 18:24:30

Biroul Național de Statistică (BNS) a recepționat varianta electronică a raportului, expediat de DVs. Urmează verificarea și validarea raportului de către specialistul BNS pe domeniu.

TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chișinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com> <tehnomedicamd@gmail.com>

Către Centrul pentru Achiziții Publice Centralizate în Sănătate

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1637327903323,
ID:21047181 din 21.12.2021

Declarație privind disponibilitatea prezentării mostrelor

Prin prezenta, declarăm că vom prezenta mostre în decurs de 5 zile de la solicitarea autorității contractante/beneficiarului pentru produsele oferite în cadrul licitației prenonate privind ***achiziționarea consumabilelor costisitoare pentru cabinetul de cardiologie intervențională, conform necesităților IMSP Spitalul Clinic Republican „Timofei Moșneaga" și IMSP Institutul Neurologie și Neurochirurgie pentru anul 2022.***

Cu respect,

Director Tatiana Roibu

21.12.2021

TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chișinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com> <tehnomedicamd@gmail.com>

Către Centrul pentru Achiziții Publice Centralizate în Sănătate

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1637327903323,
ID:21047181 din 21.12.2021

Declarație privind înregistrarea dispozitivelor medicale

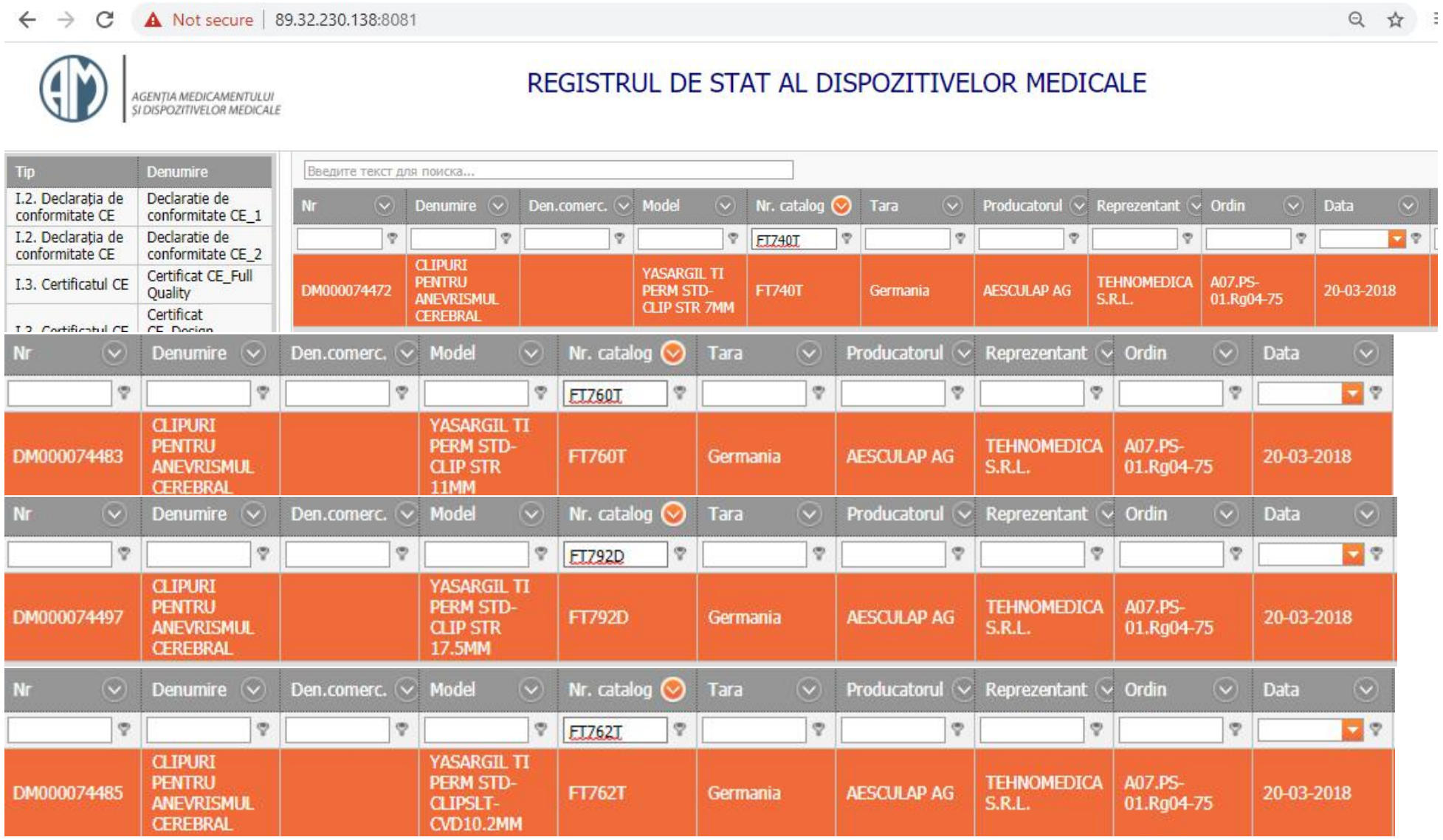
Prin prezenta, declarăm că, produsele oferite în cadrul licitației deschise prenotate sunt înregistrate în Registrul de Stat al Dispozitivelor Medicale a Agenției Medicamentului și Dispozitivelor Medicale.

Dovada înregistrării dispozitivelor medicale se regăsește pe pagina web a Agenției Medicamentului și Dispozitivelor Medicale www.amdm.gov.md

Cu respect,

Director Tatiana Roibu

Extras din Registrul de Stat al Dispozitivelor Medicale a Agenției Medicamentului și Dispozitivelor Medicale solicitat pentru **lotul 86. - Clipuri cerebrale.** Dovada înregistrării dispozitivelor medicale se regăsește pe pagina web a Agenției Medicamentului și Dispozitivelor Medicale www.amdm.gov.md



Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
				FT782T					
DM000074493	CLIPURI PENTRU ANEVRISMUL CEREBRAL		YASARGIL TI PERM STD-CLIPSLT-CVD13.7MM	FT782T	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-75	20-03-2018

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
				FT786T					
DM000074495	CLIPURI PENTRU ANEVRISMUL CEREBRAL		YASARGIL TI PERM STD-CLIPSLT-CVD15.3MM	FT786T	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-75	20-03-2018

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
				FE758K					
DM000074089	CLIPURI PENTRU ANEVRISMUL CEREBRAL		YASARGIL PERM STD-CLIP BAYO 9MM	FE758K	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-75	20-03-2018

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
				FT758T					
DM000074481	CLIPURI PENTRU ANEVRISMUL CEREBRAL		YASARGIL TI PERM STD-CLIP BAYO 9MM	FT758T	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-75	20-03-2018

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
				FT820T					
DM000074504	CLIPURI PENTRU ANEVRISMUL CEREBRAL		YASARGIL TI PERM STD-CLIP RT-ANG 7MM	FT820T	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-75	20-03-2018

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
				FE761K					
DM000074092	CLIPURI PENTRU ANEVRISMUL CEREBRAL		YASARGIL PERM STD-CLIP LAT-ANG 11.4MM	FE761K	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-75	20-03-2018

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
				FT761T					
DM000074484	CLIPURI PENTRU ANEVRISMUL CEREBRAL		YASARGIL TI PERM STD-CLIPLAT-ANG11.4MM	FT761T	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-75	20-03-2018

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
				FT644T					
DM000074448	CLIPURI PENTRU ANEVRISMUL CEREBRAL		YASARGIL TIPERM STDCLIP5.0FENF 5MM	FT644T	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-75	20-03-2018

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
				FT654T					
DM000074451	CLIPURI PENTRU ANEVRISMUL CEREBRAL		YASARGIL TIPERM STDCLIP5.0FENF	FT654T	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-75	20-03-2018

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
				FT220T					
DM000074359	CLIPURI PENTRU ANEVRISMUL CEREBRAL		YASARGIL TI TEMP MINI-CLIP STR 7MM	FT220T	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-75	20-03-2018

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
				FT710T					
DM000074459	CLIPURI PENTRU ANEVRISMUL CEREBRAL		YASARGIL TI PERM MINI-CLIP STR 5MM	FT710T	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-75	20-03-2018

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
				FT720T					
DM000074466	CLIPURI PENTRU ANEVRISMUL CEREBRAL		YASARGIL TI PERM MINI-CLIP STR 7MM	FT720T	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-75	20-03-2018
Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
				FT716T					
DM000074464	CLIPURI PENTRU ANEVRISMUL CEREBRAL		YASARGIL TI PERM MINI-CLIP LAT-ANG 5MM	FT716T	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-75	20-03-2018
Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
				FT717T					
DM000074465	CLIPURI PENTRU ANEVRISMUL CEREBRAL		YASARGIL TI PERM MINI-CLIPLAT-CVD6.3MM	FT717T	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-75	20-03-2018
Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
				FE728K					
DM000074075	CLIPURI PENTRU ANEVRISMUL CEREBRAL		YASARGIL PERM MINI-CLIP BAYO 7MM	FE728K	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-75	20-03-2018
Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
				FT728D					
DM000074471	CLIPURI PENTRU ANEVRISMUL CEREBRAL		YASARGIL TI PERM MINI-CLIP BAYO 7MM	FT728D	Germania	AESCULAP AG	TEHNOMEDICA S.R.L.	A07.PS-01.Rg04-75	20-03-2018

TEHNOMEDICA

str.Ciuflea, 38/1 MD-2001, mun. Chișinău, Moldova tel./fax: (022)601 102, 601 087
e-mail <tehnomedica_md@yahoo.com> <tehnomedicamd@gmail.com>

Către Centrul pentru Achiziții Publice
Centralizate în Sănătate

În atenția Grupului de lucru
al Licitației Deschise nr. ocds-b3wdp1-MD-1637327903323,
ID:21047181 din 21.12.2021

Declarație privind termenul de valabilitate

Prin prezenta, declarăm că termenul de valabilitate la momentul livrării a produselor oferite în cadrul licitației prenonate privind ***achiziționarea consumabilelor costisitoare pentru cabinetul de cardiologie intervențională, conform necesităților IMSP Spitalul Clinic Republican „Timofei Moșneaga" și IMSP Institutul Neurologie și Neurochirurgie pentru anul 2022*** va constitui cel puțin 80% din termenul total de valabilitate a acestora, dar nu mai mic de 12 luni.

Cu respect,

Director Tatiana Roibu

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 012974 0608 Rev. 00

Manufacturer: **B. Braun Melsungen AG**
Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Product Category(ies): **Coronary stent systems, PTCA catheters, PTA catheters, PTCA sets, Probes for stimulation and Electrophysiology, Angiography sets, manifolds, guide wires, tubes and syringes, single use Right heart pulmonary artery catheters, Monitoring sets for invasive physiological pressure measurement, Introducer sheaths and sets, Arterial puncture cannulae, arterial catheter sets**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713168177

Valid from: 2020-05-06
Valid until: 2024-05-26

Date, 2020-05-14

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 012974 0608 Rev. 00

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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 012974 0606 Rev. 00

Holder of Certificate: **B. Braun Melsungen AG**
Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and development, production and distribution of sterile single use products for angiography, surgery, angioplasty, stimulation, coronary stent systems, PTCA catheters, PTA catheters, PTCA guide wires and sets, probes for stimulation and electrophysiology, procedure kits, angiography sets, manifolds, guide wires, tubes, syringes, single use right heart pulmonary artery catheters, monitoring sets for invasive physiological pressure measurement, introducer sheaths and sets, arterial punture cannula, arterial catheter sets**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713160067

Valid from: 2019-10-08
Valid until: 2022-09-30

Date, 2019-10-08

Stefan Preiß
Head of Certification/Notified Body

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

A4 / 07.17

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D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 012974 0606 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

B. Braun Melsungen AG Vascular Systems
Sieversufer 8, 12359 Berlin, GERMANY

B. Braun Melsungen AG Vascular Systems
Mistelweg 2, 12357 Berlin, GERMANY

./.

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www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 010066 0426 Rev. 00

Manufacturer: **AESCULAP AG**
Am Aesculap-Platz
78532 Tuttlingen
GERMANY

Product Category(ies): **Implants, Instruments and Devices (for detailed information see attachment)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713159626

Valid from: 2019-07-27

Valid until: 2024-05-26

Date, 2019-07-16

Stefan Preiß
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 010066 0426 Rev. 00

Facility(ies):

AESCULAP AG
Am Aesculap-Platz, 78532 Tuttlingen, GERMANY

Surgical and dental instruments
Joint implants (hip, knee)
Spinal implants
Implants for osteosynthesis
Neurosurgical vascular implants
Products for ligature
Motor systems
High frequency surgery devices
Endoscopic systems
Navigation system
Surgical suction pumps
Implants for replacement of connective tissue
Vascular prostheses and accessories
and other surgical accessories
Collagen implants

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 010066 0435 Rev. 00

Holder of Certificate: **AESCULAP AG**
Am Aesculap-Platz
78532 Tuttlingen
GERMANY

Certification Mark:

Scope of Certificate: **Design and development, production, technical service and distribution of implants, instruments, instrument management systems, containers, devices, tissue adhesives**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713175266

Valid from: 2020-06-01
Valid until: 2023-05-31

Date, 2020-05-27

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 010066 0435 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

AESCULAP AG
Am Aesculap-Platz, 78532 Tuttlingen, GERMANY

AESCULAP AG
Carl-Braun-Str. 1, 34212 Melsungen, GERMANY

- Surgical and dental instruments
- Joint implants (hip, knee)
- Spinal implants
- Implants for osteosynthesis
- Neurosurgical vascular implants
- Products for ligature
- Motor systems
- Sterilization containers and accessories
- High frequency surgery devices
- Endoscopie systems
- Navigation systems
- Surgical suction pumps
- Implants for replacement of connective tissue
- Tissue adhesives
- Vascular prostheses and accessories
- Local haemostatics
- Other surgical accessories
- Collagen implants

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

Aesculap AG

Am Aesculap-Platz, 78532 Tuttlingen, Germany
Carl-Braun-Straße 1, 34212 Melsungen, Germany

has established and applies
a Quality Management System for

Design and Development, Technical Service, Production and Distribution of Implants, Instruments, Containers, Devices, Suture Material and Tissue Adhesive

Aesculap AG Tuttlingen

- Surgical and dental instruments
- Joint Implants (hip, knee)
- Spinal Implants
- Implants for Osteosynthesis
- Neurosurgical Vascular Implants
- Motor systems
- Sterilization containers and accessories
- High frequency surgery devices
- Endoscopie systems
- Navigation systems
- Surgical suction pumps
- Veterinary instrumentation
- Other surgical accessories
- Instrument Management System
- Collagen implants

Aesculap AG Melsungen

- Implants for replacement of connective tissue
- Tissue adhesive
- Local haemostatic

An audit was performed, Order No. **70062209**.

Proof has been furnished that the requirements according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2020-06-01** until **2023-05-31**.

Certificate Registration No.: **12 100 21724 TMS**.

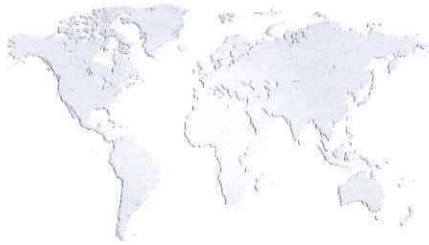
Product Compliance Management
Munich, 2020-05-20

DAkkS Deutsche Akkreditierungsstelle D-ZM-14143-01-00

MS/01-01/2019

EC CERTIFICATE

for the Quality Assurance System



according the Directive 93/42/EEC, Annex II excluding section (4)

As a Notified Body of the European Union, DEKRA Certification GmbH certifies, that the company

optimed Medizinische Instrumente GmbH

Ferdinand-Porsche-Straße 11, 76275 Ettlingen, Germany

Certified location:

Ferdinand-Porsche-Straße 11, 76275 Ettlingen, Germany

applies a quality assurance system according to the Directive 93/42/EEC Annex II for the medical devices listed in the annex. The approval is based on the result of the re-certification audit report no. 50066-Z6-00, the decision dated 2019-06-26 and is only valid in connection with the successful performance of the annual surveillance audits.

This certificate is valid from 2019-08-05 to 2024-05-26

Registration No.: 50066-16-08

DEKRA Certification GmbH D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH Stuttgart; 2019-06-26
Notified Body ID-number: 0124

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-295.10.02

844460

Annex to the EC Certificate No. 50066-16-08

Valid from 2019-08-05 to 2024-05-26

Revision status of the annex: 1 dated 2020-04-22

Devices/device categories included in the certificate:

Class I s:

For the products listed below, review of the Quality Assurance System refers exclusively to aspects of manufacture concerned with securing and maintaining sterile conditions.

- Ureteral Catheters and Sets
- Non-Invasive Accessories
    - Connectors
    - Adapters

Class II a:

- Radiological Catheters
    - Balloon Catheters
    - Lysis Catheters
    - Aspiration Catheters and Sets
- CO_2-Angioset
- Needles and Systems
    - Interventional Needles
- TIPS Puncture Needles and Sets
- Stone Baskets
- Invasive / surgical invasive Accessories
    - Dilators
    - Pushers
    - Introducers
- Non-invasive Accessories
    - Stopcocks
    - Haemostatic Valves
- Percutaneous Drainages
    - Catheters and Sets
- Drainages and Sets
    - Biliary Endoprostheses
    - Pancreatic Stent
- Urological Balloon Catheters and Sets
- Hydrophilic coated Nitinol Guide Wires

Class II b:

- Implants: Nitinol Stents
    - sinus-Endoscopic
    - sinus-Repo-Visual 6F
    - sinus-Reduction
    - sinus-SuperFlex-418
    - sinus-SuperFlex-518
    - sinus-SuperFlex 535
    - sinus-SuperFlex-635
    - sinus-Venous
    - sinus-Obliquus
    - Tentos 4F / Tentos 5F

Annex to the EC Certificate No. 50066-16-08

Valid from 2019-08-05 to 2024-05-26

Revision status of the annex: 1 dated 2020-04-22

Devices/device categories included in the certificate:

Class II b:

- Ureteral Stents and Sets
- Spine
  - Injection Instruments and Sets
  - Adapters
  - Needles and Accessories

Class III:

- Implants: Nitinol Stents
  - sinus-XL, sinus-XL Flex, sinus-XL 6F
  - sinus-SuperFlex-DS, sinus-Repo-DS

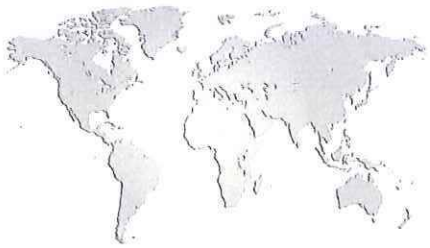
- Radiological Catheters
  - DSA Premium Catheters and Sets
  - Angiography Catheters and Sets
  - Balloon Catheters
- PTFE-coated Guide Wires (Stainless Steel, Nitinol)
- Exchange Guide Wires (Stainless Steel)

For the placing on the market of class III devices covered by this certificate an EC design-examination certificate according to directive 93/42/EEC annex II (4) is required.

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 D-70565

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2020-04-22
Notified Body ID-number: 0124

CERTIFICATE



EN ISO 13485:2016

DEKRA Certification GmbH hereby certifies that the organization

optimed Medizinische Instrumente GmbH

Scope of certification:

Development, manufacturing, sterilization and distribution of medical products for vascular interventions, gastroenterology, urology, spine as well as minimally invasive instruments

Certified location:

Ferdinand-Porsche-Straße 11, 76275 Ettlingen, Germany

(further locations see annex)

has established and maintains a quality management system according to the above mentioned standard. The conformity was adduced with audit report no. 50066-Z6-00.

Certificate registration no.:	50066-14-01	Certificate valid from:	2019-08-05
Validity of previous certificate:	2019-08-04	Certificate valid to:	2022-08-04

DEKRA Certification GmbH Stuttgart, Handwerkstraße 15 D-70565 DEKRA Certification

DAkkS Deutsche Akkreditierungsstelle D-ZM-16029-08-00

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2019-06-26

Annex to the Certificate No. 50066-14-01

Revision status: 0

valid from 2019-08-05 to 2022-08-04

The following locations belong to the certificate above:

	Headquarters	Certified location	Scope of certification
	optimed Medizinische Instrumente GmbH	Ferdinand-Porsche-Straße 11 D-76275 Ettlingen	Development, manufacturing, sterilization and distribution of medical products for vascular interventions, gastroenterology, urology, spine as well as minimally invasive instruments
	Subsidiaries	**Certified locations**	**Scope of certification**
1.	optimed Medizinische Instrumente GmbH	Ferdinand-Porsche-Straße 9, D-76275 Ettlingen	Development, manufacturing, sterilization and distribution of medical products for vascular interventions, gastroenterology, urology, spine as well as minimally invasive instruments
2.	optimed Medizinische Instrumente GmbH	Otto-Hahn-Straße 18 D-76275 Ettlingen	Development, manufacturing, sterilization and distribution of medical products for vascular interventions, gastroenterology, urology, spine as well as minimally invasive instruments

DEKRA Certification GmbH
DEKRA Certification
D-70565 Stuttgart, Handwerkstraße 15

Ruth Delbeck-Bayer
DEKRA Certification GmbH, Stuttgart, 2019-06-26

8. Declaration of Conformity

DECLARATION OF CONFORMITY

optimed Medizinische Instrumente GmbH
Ferdinand-Porsche-Straße 11
76275 Ettlingen

hereby declares in its own responsibility that

SINUS-SUPERFLEX-535

Order codes:
Please refer to the annexed article range
of TD1031_1.1.7, Rev. 2

is a Class IIb medical device
reviewed in accordance with Annex II excluding section (IV)

0124

DEKRA Certification GmbH
Handwerkstrasse 15
D-70565 Stuttgart

conforming to the relevant provisions of the Directive 93/42/EEC.
This Declaration of Conformity is valid until 26.05.2024.
The validity corresponds to the validity of the CE-certificate number 50066-16-08.

Ettlingen, 25.06.2021

Frank Wohkittel

Head of Regulatory Affairs

optimed
Medizinische Instrumente GmbH
Ferdinand-Porsche-Straße 11
76275 Ettlingen · Germany
Phone +49(0)7243 /7633-0
Fax +49(0)7243/7633-99

1.1.7 Complete List of the Various Configurations and Variants

The optimed sinus-SuperFlex-535 stent system is available in stent diameters from 4 mm up to 10 mm and in stent length from 20 mm up to 80 mm.

The following table shows the complete list of stent sizes:

Order Code	Specification
6104-6030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 4 mm L: 30 mm, application device D: 5 F L: 75 cm
6104-6040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 4 mm L: 40 mm, application device D: 5 F L: 75 cm
6104-6060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 4 mm L: 60 mm, application device D: 5 F L: 75 cm
6104-6080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 4 mm L: 80 mm, application device D: 5 F L: 75 cm
6104-7030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 4 mm L: 30 mm, application device D: 5 F L: 120 cm
6104-7040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 4 mm L: 40 mm, application device D: 5 F L: 120 cm
6104-7060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 4 mm L: 60 mm, application device D: 5 F L: 120 cm
6104-7080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 4 mm L: 80 mm, application device D: 5 F L: 120 cm
6105-6030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 5 mm L: 30 mm, application device D: 5 F L: 75 cm
6105-6040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 5 mm L: 40 mm, application device D: 5 F L: 75 cm
6105-6060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 5 mm L: 60 mm, application device D: 5 F L: 75 cm
6105-6080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 5 mm L: 80 mm, application device D: 5 F L: 75 cm
6105-7030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 5 mm L: 30 mm, application device D: 5 F L: 120 cm
6105-7040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 5 mm L: 40 mm, application device D: 5 F L: 120 cm
6105-7060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 5 mm L: 60 mm, application device D: 5 F L: 120 cm
6105-7080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 5 mm L: 80 mm, application device D: 5 F L: 120 cm

6106-6020	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 6 mm L: 20 mm, application device D: 5 F L: 75 cm
6106-6030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 6 mm L: 30 mm, application device D: 5 F L: 75 cm
6106-6040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 6 mm L: 40 mm, application device D: 5 F L: 75 cm
6106-6060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 6 mm L: 60 mm, application device D: 5 F L: 75 cm
6106-6080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 6 mm L: 80 mm, application device D: 5 F L: 75 cm
6106-7020	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 6 mm L: 20 mm, application device D: 5 F L: 120 cm
6106-7030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 6 mm L: 30 mm, application device D: 5 F L: 120 cm
6106-7040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 6 mm L: 40 mm, application device D: 5 F L: 120 cm
6106-7060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 6 mm L: 60 mm, application device D: 5 F L: 120 cm
6106-7080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 6 mm L: 80 mm, application device D: 5 F L: 120 cm
6107-6020	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 7 mm L: 20 mm, application device D: 5 F L: 75 cm
6107-6030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 7 mm L: 30 mm, application device D: 5 F L: 75 cm
6107-6040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 7 mm L: 40 mm, application device D: 5 F L: 75 cm
6107-6060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 7 mm L: 60 mm, application device D: 5 F L: 75 cm
6107-6080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 7 mm L: 80 mm, application device D: 5 F L: 75 cm
6107-7020	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 7 mm L: 20 mm, application device D: 5 F L: 120 cm
6107-7030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 7 mm L: 30 mm, application device D: 5 F L: 120 cm
6107-7040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 7 mm L: 40 mm, application device D: 5 F L: 120 cm
6107-7060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 7 mm L: 60 mm, application device D: 5 F L: 120 cm
6107-7080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 7 mm L: 80 mm, application device D: 5 F L: 120 cm
6108-6020	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 8 mm L: 20 mm, application device D: 5 F L: 75 cm

6108-6030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 8 mm L: 30 mm, application device D: 5 F L: 75 cm
6108-6040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 8 mm L: 40 mm, application device D: 5 F L: 75 cm
6108-6060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 8 mm L: 60 mm, application device D: 5 F L: 75 cm
6108-6080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 8 mm L: 80 mm, application device D: 5 F L: 75 cm
6108-7020	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 8 mm L: 20 mm, application device D: 5 F L: 120 cm
6108-7030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 8 mm L: 30 mm, application device D: 5 F L: 120 cm
6108-7040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 8 mm L: 40 mm, application device D: 5 F L: 120 cm
6108-7060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 8 mm L: 60 mm, application device D: 5 F L: 120 cm
6108-7080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 8 mm L: 80 mm, application device D: 5 F L: 120 cm
6109-6020	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 9 mm L: 20 mm, application device D: 5 F L: 75 cm
6109-6030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 9 mm L: 30 mm, application device D: 5 F L: 75 cm
6109-6040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 9 mm L: 40 mm, application device D: 5 F L: 75 cm
6109-6060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 9 mm L: 60 mm, application device D: 5 F L: 75 cm
6109-6080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 9 mm L: 80 mm, application device D: 5 F L: 75 cm
6109-7020	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 9 mm L: 20 mm, application device D: 5 F L: 120 cm
6109-7030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 9 mm L: 30 mm, application device D: 5 F L: 120 cm
6109-7040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 9 mm L: 40 mm, application device D: 5 F L: 120 cm
6109-7060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 9 mm L: 60 mm, application device D: 5 F L: 120 cm
6109-7080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 9 mm L: 80 mm, application device D: 5 F L: 120 cm
6110-6020	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 10 mm L: 20 mm, application device D: 5 F L: 75 cm
6110-6030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 10 mm L: 30 mm, application device D: 5 F L: 75 cm

6110-6040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 10 mm L: 40 mm, application device D: 5 F L: 75 cm
6110-6060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 10 mm L: 60 mm, application device D: 5 F L: 75 cm
6110-6080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 10 mm L: 80 mm, application device D: 5 F L: 75 cm
6110-7020	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 10 mm L: 20 mm, application device D: 5 F L: 120 cm
6110-7030	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 10 mm L: 30 mm, application device D: 5 F L: 120 cm
6110-7040	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 10 mm L: 40 mm, application device D: 5 F L: 120 cm
6110-7060	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 10 mm L: 60 mm, application device D: 5 F L: 120 cm
6110-7080	sinus-SuperFlex-535; Stent system, Nitinol, vascular / biliary; Stent D: 10 mm L: 80 mm, application device D: 5 F L: 120 cm

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	170738217
Effective date	2019-03-12
Expiry date	2022-06-28
Frankfurt am Main	2019-03-12

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: 170738217
Effective date: 2019-03-12

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
	Acclino® peripher Stent	IIb	46352
	Acandis® BTK flex Stent	IIb	46352
Accero® Stent	Accero® Stent	III	46352
	Accero® Stent System	III	46352
Aperio® Recanalisation Device	Aperio® Thrombectomy Device	III	61779
	Aperio® Hybrid Thrombectomy Device	III	61779
Credo® Stent	Credo® Stent	III	46352

CERTIFICATE

This is to certify that the company

Acandis GmbH

Theodor-Fahrner-Strasse 6
75177 Pforzheim
Germany

has implemented and maintains a **Quality Management System**.

Scope:
Design and Development, Manufacturing, Sales and Final Control of Product Categories Catheters, Stents, Stent Delivery Systems and endovascular Medical Devices for neurosurgical cardiological and peripheral Applications.

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

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	516802 MP2016
Certificate unique ID	170774421
Effective date	2021-06-19
Expiry date	2024-06-18
Frankfurt am Main	2021-04-28

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16021-01-00

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

410.90.en Version 1.0

Declaration of Conformity

according to directive 93/42/EEC

Product	**ACCERO® Stent & 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 2024-05-26
EC Design Examination Certificate	No. 517166 MRA valid until 2024-05-26
Declaration of Conformity valid until	2024-05-26

Pforzheim, 2021-05-25

.....

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
01-000803	ACCERO® Stent	3.0 mm x 10 mm
01-000804	ACCERO® Stent	3.0 mm x 15 mm
01-000805	ACCERO® Stent	3.0 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
01-000810	ACCERO® Stent	4.0 mm x 15 mm
01-000811	ACCERO® Stent	4.0 mm x 20 mm
01-000845	ACCERO® Stent	4.0 mm x 25 mm
01-000813	ACCERO® Stent	4.5 mm x 15 mm
01-000814	ACCERO® Stent	4.5 mm x 20 mm
01-000815	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
01-000818	ACCERO® Stent System	3.0 mm x 10 mm
01-000819	ACCERO® Stent System	3.0 mm x 15 mm
01-000820	ACCERO® Stent System	3.0 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
01-000825	ACCERO® Stent System	4.0 mm x 15 mm
01-000826	ACCERO® Stent System	4.0 mm x 20 mm
01-000846	ACCERO® Stent System	4.0 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

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 2024-05-26
EC Design Examination Certificate	No. 515356 MRA valid until 2024-01-13
Declaration of Conformity valid until	2024-01-13

Pforzheim, 2021-05-25

Stefan Höfele
Director Regulatory Affairs

Declaration of Conformity ACCLINO® flex plus Stent

Product listing

Article number	Name	Size
01-001122	ACCLINO® flex plus Stent	3.0mm x 15mm
01-001123	ACCLINO® flex plus Stent	3.0mm x 20mm
01-001124	ACCLINO® flex plus Stent	3.0mm x 25mm
01-001125	ACCLINO® flex plus Stent	3.0mm x 30mm
01-001126	ACCLINO® flex plus Stent	3.0mm x 35mm
01-001132	ACCLINO® flex plus Stent	3.5mm x 15mm
01-001133	ACCLINO® flex plus Stent	3.5mm x 20mm
01-001134	ACCLINO® flex plus Stent	3.5mm x 25mm
01-001135	ACCLINO® flex plus Stent	3.5mm x 30mm
01-001136	ACCLINO® flex plus Stent	3.5mm x 35mm
01-001142	ACCLINO® flex plus Stent	4.0mm x 15mm
01-001143	ACCLINO® flex plus Stent	4.0mm x 20mm
01-001144	ACCLINO® flex plus Stent	4.0mm x 25mm
01-001145	ACCLINO® flex plus Stent	4.0mm x 30mm
01-001146	ACCLINO® flex plus Stent	4.0mm x 35mm
01-001152	ACCLINO® flex plus Stent	4.5mm x 15mm
01-001153	ACCLINO® flex plus Stent	4.5mm x 20mm
01-001154	ACCLINO® flex plus Stent	4.5mm x 25mm
01-001155	ACCLINO® flex plus Stent	4.5mm x 30mm
01-001156	ACCLINO® flex plus Stent	4.5mm x 35mm
01-001162	ACCLINO® flex plus Stent	5.0mm x 15mm
01-001163	ACCLINO® flex plus Stent	5.0mm x 20mm
01-001164	ACCLINO® flex plus Stent	5.0mm x 25mm
01-001165	ACCLINO® flex plus Stent	5.0mm x 30mm
01-001166	ACCLINO® flex plus Stent	5.0mm x 35mm
01-001173	ACCLINO® flex plus Stent	5.5mm x 20mm
01-001174	ACCLINO® flex plus Stent	5.5mm x 25mm
01-001175	ACCLINO® flex plus Stent	5.5mm x 30mm
01-001176	ACCLINO® flex plus Stent	5.5mm x 35mm
01-001193	ACCLINO® flex plus Stent	6.5mm x 20mm
01-001194	ACCLINO® flex plus Stent	6.5mm x 25mm
01-001195	ACCLINO® flex plus Stent	6.5mm x 30mm
01-001196	ACCLINO® flex plus Stent	6.5mm x 35mm
01-001213	ACCLINO® flex plus Stent	8.0mm x 20mm
01-001215	ACCLINO® flex plus Stent	8.0mm x 30mm
01-001217	ACCLINO® flex plus Stent	8.0mm x 40mm
01-001221	ACCLINO® flex plus Stent	8.0mm x 60mm

Declaration of Conformity

according to directive 93/42/EEC

Product	**DERIVO® 2 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 2024-05-26
EC Design Examination Certificate	No. 513562 MRA valid until 2023-08-25
Declaration of Conformity valid until	2023-08-25

Pforzheim, 2021-05-25

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Stefan Höfele
Director Regulatory Affairs

Declaration of Conformity DERIVO® 2 Embolisation Device & System

Product listing

Article number	Name	Size
01-107001	DERIVO® 2 Embolisation Device short tip	2.5 mm x 10 mm
01-107002	DERIVO® 2 Embolisation Device short tip	2.5 mm x 15 mm
01-107003	DERIVO® 2 Embolisation Device short tip	2.5 mm x 20 mm
01-107004	DERIVO® 2 Embolisation Device short tip	2.5 mm x 25 mm
01-107005	DERIVO® 2 Embolisation Device short tip	3.0 mm x 10 mm
01-107006	DERIVO® 2 Embolisation Device short tip	3.0 mm x 15 mm
01-107007	DERIVO® 2 Embolisation Device short tip	3.0 mm x 20 mm
01-107008	DERIVO® 2 Embolisation Device short tip	3.0 mm x 25 mm
01-107009	DERIVO® 2 Embolisation Device short tip	3.5 mm x 10 mm
01-107010	DERIVO® 2 Embolisation Device short tip	3.5 mm x 15 mm
01-107011	DERIVO® 2 Embolisation Device short tip	3.5 mm x 20 mm
01-107012	DERIVO® 2 Embolisation Device short tip	3.5 mm x 25 mm
01-107013	DERIVO® 2 Embolisation Device	3.5 mm x 30 mm
01-107014	DERIVO® 2 Embolisation Device	4.0 mm x 15 mm
01-107015	DERIVO® 2 Embolisation Device	4.0 mm x 20 mm
01-107016	DERIVO® 2 Embolisation Device	4.0 mm x 25 mm
01-107017	DERIVO® 2 Embolisation Device	4.0 mm x 30 mm
01-107018	DERIVO® 2 Embolisation Device	4.5 mm x 15 mm
01-107019	DERIVO® 2 Embolisation Device	4.5 mm x 20 mm
01-107020	DERIVO® 2 Embolisation Device	4.5 mm x 25 mm
01-107021	DERIVO® 2 Embolisation Device	4.5 mm x 30 mm
01-107022	DERIVO® 2 Embolisation Device	5.0 mm x 15 mm
01-107023	DERIVO® 2 Embolisation Device	5.0 mm x 20 mm
01-107024	DERIVO® 2 Embolisation Device	5.0 mm x 25 mm
01-107025	DERIVO® 2 Embolisation Device	5.0 mm x 30 mm
01-107026	DERIVO® 2 Embolisation Device	5.5 mm x 15 mm
01-107027	DERIVO® 2 Embolisation Device	5.5 mm x 20 mm
01-107028	DERIVO® 2 Embolisation Device	5.5 mm x 25 mm
01-107029	DERIVO® 2 Embolisation Device	5.5 mm x 30 mm

Article number	Name	Size
01-107030	DERIVO® 2 Embolisation Device	6.0 mm x 15 mm
01-107031	DERIVO® 2 Embolisation Device	6.0 mm x 20 mm
01-107032	DERIVO® 2 Embolisation Device	6.0 mm x 25 mm
01-107033	DERIVO® 2 Embolisation Device	6.0 mm x 30 mm
01-107034	DERIVO® 2 Embolisation Device short tip	3.5 mm x 30 mm
01-107035	DERIVO® 2 Embolisation Device short tip	3.5 mm x 40 mm
01-107036	DERIVO® 2 Embolisation Device short tip	4.0 mm x 20 mm
01-107037	DERIVO® 2 Embolisation Device short tip	4.0 mm x 25 mm
01-107038	DERIVO® 2 Embolisation Device short tip	4.0 mm x 30 mm
01-107039	DERIVO® 2 Embolisation Device short tip	4.0 mm x 40 mm
01-107040	DERIVO® 2 Embolisation Device short tip	4.5 mm x 20 mm
01-107041	DERIVO® 2 Embolisation Device short tip	4.5 mm x 25 mm
01-107042	DERIVO® 2 Embolisation Device short tip	4.5 mm x 30 mm
01-107043	DERIVO® 2 Embolisation Device short tip	4.5 mm x 40 mm
01-107044	DERIVO® 2 Embolisation Device short tip	5.0 mm x 20 mm
01-107045	DERIVO® 2 Embolisation Device short tip	5.0 mm x 25 mm
01-107046	DERIVO® 2 Embolisation Device short tip	5.0 mm x 30 mm
01-107047	DERIVO® 2 Embolisation Device short tip	5.0 mm x 40 mm
01-107048	DERIVO® 2 Embolisation Device short tip	5.0 mm x 50 mm
01-107049	DERIVO® 2 Embolisation Device short tip	5.5 mm x 20 mm
01-107050	DERIVO® 2 Embolisation Device short tip	5.5 mm x 25 mm
01-107051	DERIVO® 2 Embolisation Device short tip	5.5 mm x 30 mm
01-107052	DERIVO® 2 Embolisation Device short tip	5.5 mm x 40 mm
01-107053	DERIVO® 2 Embolisation Device short tip	5.5 mm x 50 mm
01-107054	DERIVO® 2 Embolisation Device short tip	6.0 mm x 20 mm
01-107055	DERIVO® 2 Embolisation Device short tip	6.0 mm x 25 mm
01-107056	DERIVO® 2 Embolisation Device short tip	6.0 mm x 30 mm
01-107057	DERIVO® 2 Embolisation Device short tip	6.0 mm x 40 mm
01-107058	DERIVO® 2 Embolisation Device short tip	6.0 mm x 50 mm
01-107059	DERIVO® 2 Embolisation Device	7.0 mm x 20 mm
01-107060	DERIVO® 2 Embolisation Device	7.0 mm x 25 mm
01-107061	DERIVO® 2 Embolisation Device	7.0 mm x 30 mm

Article number	Name	Size
01-107062	DERIVO® 2 Embolisation Device	8.0 mm x 20 mm
01-107063	DERIVO® 2 Embolisation Device	8.0 mm x 25 mm
01-107064	DERIVO® 2 Embolisation Device	8.0 mm x 30 mm
01-107065	DERIVO® 2 Embolisation Device short tip	7.0 mm x 20 mm
01-107066	DERIVO® 2 Embolisation Device short tip	7.0 mm x 25 mm
01-107067	DERIVO® 2 Embolisation Device short tip	7.0 mm x 30 mm
01-107068	DERIVO® 2 Embolisation Device short tip	7.0 mm x 40 mm
01-107069	DERIVO® 2 Embolisation Device short tip	7.0 mm x 50 mm
01-107070	DERIVO® 2 Embolisation Device short tip	8.0 mm x 20 mm
01-107071	DERIVO® 2 Embolisation Device short tip	8.0 mm x 25 mm
01-107072	DERIVO® 2 Embolisation Device short tip	8.0 mm x 30 mm
01-107073	DERIVO® 2 Embolisation Device short tip	8.0 mm x 40 mm
01-107074	DERIVO® 2 Embolisation Device short tip	8.0 mm x 50 mm
01-107101	DERIVO® 2 Embolisation System short tip	2.5 mm x 10 mm
01-107102	DERIVO® 2 Embolisation System short tip	2.5 mm x 15 mm
01-107103	DERIVO® 2 Embolisation System short tip	2.5 mm x 20 mm
01-107104	DERIVO® 2 Embolisation System short tip	2.5 mm x 25 mm
01-107105	DERIVO® 2 Embolisation System short tip	3.0 mm x 10 mm
01-107106	DERIVO® 2 Embolisation System short tip	3.0 mm x 15 mm
01-107107	DERIVO® 2 Embolisation System short tip	3.0 mm x 20 mm
01-107108	DERIVO® 2 Embolisation System short tip	3.0 mm x 25 mm
01-107109	DERIVO® 2 Embolisation System short tip	3.5 mm x 10 mm
01-107110	DERIVO® 2 Embolisation System short tip	3.5 mm x 15 mm
01-107111	DERIVO® 2 Embolisation System short tip	3.5 mm x 20 mm
01-107112	DERIVO® 2 Embolisation System short tip	3.5 mm x 25 mm
01-107113	DERIVO® 2 Embolisation System	3.5 mm x 30 mm
01-107114	DERIVO® 2 Embolisation System	4.0 mm x 15 mm
01-107115	DERIVO® 2 Embolisation System	4.0 mm x 20 mm
01-107116	DERIVO® 2 Embolisation System	4.0 mm x 25 mm
01-107117	DERIVO® 2 Embolisation System	4.0 mm x 30 mm
01-107118	DERIVO® 2 Embolisation System	4.5 mm x 15 mm

Article number	Name	Size
01-107119	DERIVO® 2 Embolisation System	4.5 mm x 20 mm
01-107120	DERIVO® 2 Embolisation System	4.5 mm x 25 mm
01-107121	DERIVO® 2 Embolisation System	4.5 mm x 30 mm
01-107122	DERIVO® 2 Embolisation System	5.0 mm x 15 mm
01-107123	DERIVO® 2 Embolisation System	5.0 mm x 20 mm
01-107124	DERIVO® 2 Embolisation System	5.0 mm x 25 mm
01-107125	DERIVO® 2 Embolisation System	5.0 mm x 30 mm
01-107126	DERIVO® 2 Embolisation System	5.5 mm x 15 mm
01-107127	DERIVO® 2 Embolisation System	5.5 mm x 20 mm
01-107128	DERIVO® 2 Embolisation System	5.5 mm x 25 mm
01-107129	DERIVO® 2 Embolisation System	5.5 mm x 30 mm
01-107130	DERIVO® 2 Embolisation System	6.0 mm x 15 mm
01-107131	DERIVO® 2 Embolisation System	6.0 mm x 20 mm
01-107132	DERIVO® 2 Embolisation System	6.0 mm x 25 mm
01-107133	DERIVO® 2 Embolisation System	6.0 mm x 30 mm
01-107134	DERIVO® 2 Embolisation System short tip	3.5 mm x 30 mm
01-107135	DERIVO® 2 Embolisation System short tip	3.5 mm x 40 mm
01-107136	DERIVO® 2 Embolisation System short tip	4.0 mm x 20 mm
01-107137	DERIVO® 2 Embolisation System short tip	4.0 mm x 25 mm
01-107138	DERIVO® 2 Embolisation System short tip	4.0 mm x 30 mm
01-107139	DERIVO® 2 Embolisation System short tip	4.0 mm x 40 mm
01-107140	DERIVO® 2 Embolisation System short tip	4.5 mm x 20 mm
01-107141	DERIVO® 2 Embolisation System short tip	4.5 mm x 25 mm
01-107142	DERIVO® 2 Embolisation System short tip	4.5 mm x 30 mm
01-107143	DERIVO® 2 Embolisation System short tip	4.5 mm x 40 mm
01-107144	DERIVO® 2 Embolisation System short tip	5.0 mm x 20 mm
01-107145	DERIVO® 2 Embolisation System short tip	5.0 mm x 25 mm
01-107146	DERIVO® 2 Embolisation System short tip	5.0 mm x 30 mm
01-107147	DERIVO® 2 Embolisation System short tip	5.0 mm x 40 mm
01-107148	DERIVO® 2 Embolisation System short tip	5.0 mm x 50 mm
01-107149	DERIVO® 2 Embolisation System short tip	5.5 mm x 20 mm
01-107150	DERIVO® 2 Embolisation System short tip	5.5 mm x 25 mm

Article number	Name	Size
01-107151	DERIVO® 2 Embolisation System short tip	5.5 mm x 30 mm
01-107152	DERIVO® 2 Embolisation System short tip	5.5 mm x 40 mm
01-107153	DERIVO® 2 Embolisation System short tip	5.5 mm x 50 mm
01-107154	DERIVO® 2 Embolisation System short tip	6.0 mm x 20 mm
01-107155	DERIVO® 2 Embolisation System short tip	6.0 mm x 25 mm
01-107156	DERIVO® 2 Embolisation System short tip	6.0 mm x 30 mm
01-107157	DERIVO® 2 Embolisation System short tip	6.0 mm x 40 mm
01-107158	DERIVO® 2 Embolisation System short tip	6.0 mm x 50 mm
01-107159	DERIVO® 2 Embolisation System	7.0 mm x 20 mm
01-107160	DERIVO® 2 Embolisation System	7.0 mm x 25 mm
01-107161	DERIVO® 2 Embolisation System	7.0 mm x 30 mm
01-107162	DERIVO® 2 Embolisation System	8.0 mm x 20 mm
01-107163	DERIVO® 2 Embolisation System	8.0 mm x 25 mm
01-107164	DERIVO® 2 Embolisation System	8.0 mm x 30 mm
01-107165	DERIVO® 2 Embolisation System short tip	7.0 mm x 20 mm
01-107166	DERIVO® 2 Embolisation System short tip	7.0 mm x 25 mm
01-107167	DERIVO® 2 Embolisation System short tip	7.0 mm x 30 mm
01-107168	DERIVO® 2 Embolisation System short tip	7.0 mm x 40 mm
01-107169	DERIVO® 2 Embolisation System short tip	7.0 mm x 50 mm
01-107170	DERIVO® 2 Embolisation System short tip	8.0 mm x 20 mm
01-107171	DERIVO® 2 Embolisation System short tip	8.0 mm x 25 mm
01-107172	DERIVO® 2 Embolisation System short tip	8.0 mm x 30 mm
01-107173	DERIVO® 2 Embolisation System short tip	8.0 mm x 40 mm
01-107174	DERIVO® 2 Embolisation System short tip	8.0 mm x 50 mm

Declaration of Conformity

according to directive 93/42/EEC

Product	**NeuroBridge® Intermediate Catheter** Product listing see page 2
Class	**III** **Rule 7, bullet point 2,** **according to directive 93/42/EEC annex IX**
UMDNS/GMDN-No.	**17-846/17846**
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 2024-05-26
EC Design Examination Certificate	No. 513725 MRA valid until 2023-11-02
Declaration of Conformity valid	2023-11-02

Pforzheim, 2021-05-25

Stefan Höfele
Director Regulatory Affairs

Declaration of Conformity NeuroBridge® Intermediate Catheter

Product listing

Article number	Name	Size
01-000500	NeuroBridge® 39	125cm, straight
01-000501	NeuroBridge® 39	135cm, straight
01-000502	NeuroBridge® 39	145cm, straight
01-000503	NeuroBridge® 52	115cm, straight
01-000504	NeuroBridge® 52	125cm, straight
01-000505	NeuroBridge® 52	135cm, straight
01-000506	NeuroBridge® 65	115cm, straight
01-000507	NeuroBridge® 65	125cm, straight
01-000508	NeuroBridge® 39	125cm, Multi-Purpose 25°
01-000509	NeuroBridge® 39	135cm, Multi-Purpose 25°
01-000510	NeuroBridge® 39	145cm, Multi-Purpose 25°
01-000511	NeuroBridge® 52	115cm, Multi-Purpose 25°
01-000512	NeuroBridge® 52	125cm, Multi-Purpose 25°
01-000513	NeuroBridge® 52	135cm, Multi-Purpose 25°
01-000514	NeuroBridge® 65	115cm, Multi-Purpose 25°
01-000515	NeuroBridge® 65	125cm, Multi-Purpose 25°
01-000516	NeuroBridge® 52	105cm, straight
01-000517	NeuroBridge® 65	105cm, straight
01-000518	NeuroBridge® 52	105cm, Multi-Purpose 25°
01-000519	NeuroBridge® 65	105cm, Multi-Purpose 25°

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 2024-05-26
EC Design Examination Certificate	No. 376850 MRA valid until 2023-03-15
Declaration of Conformity valid until	2023-03-15

Pforzheim, 2021-05-25

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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"

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 2024-05-26
EC Design Examination Certificate	No. 516771 MRA valid until 2024-05-26
Declaration of Conformity valid until	2024-05-26

Pforzheim, 2021-05-25

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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

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® 17 Microcatheter, NeuroSlider® 21 Microcatheter, NeuroSlider® 27 Microcatheter NeuroSlider® 17 Microcatheter DLC and NeuroSlider® 21 Microcatheter DLC

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: Produktakte B Zusammenfassung TD NeuroSlider dated 2018-02-07
STED_CE-Approval_NeuroSlider DLC-E_A dated 2019-03-19
411_18e_Report_TFR_Sterilization Inpac_V1 dated 2019-09-23

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
411_18d_Bericht_NeuroSlider_V2 dated 2019-05-13
10_411e_Report_TFR_SterilizationInpac_V1 dated 2019-10-19

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	170755464
Effective date	2019-10-19
Expiry date	2023-03-15
Frankfurt am Main	2019-10-19

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)

Derivo® Embolisation Device and Derivo® Embolisation System
Derivo® 2 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
STED_CE-Approval_Derivo Embolisation Device-E_A dated 2019-08-15
411_18e_Report_TFR_Sterilization Inpac_V1 dated 2019-09-23
STED_CE-Approval_Derivo 2 Embolisation Device-E_A dated 2019-10-02

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
411_18e_Report_TFR_Derivo_V3 dated 2019-09-06
10_411_18e_Report_TFR_SterilizationInpac_V1 dated 2019-10-19
0_411_18e_Report_TFR_Derivo2_V1.docx dated 2020-03-26

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	170767288
Effective date	2020-03-26
Expiry date	2023-08-25
Frankfurt am Main	2020-03-26

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)

NeuroBridge® Catheter NeuroBridge® A70 Catheter NeuroBridge® S39 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
411_18e_Report_TFR_Sterilization Inpac_V1 dated 2019-09-23
STED_CE-Approval_NeuroBridge A70-E_A dated 2019-10-25
STED_CE-Approval_NeuroBridge S39-E_A dated 2019-10-25

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
10_411_18e_Report_TFR_SterilizationInpac_V1 dated 2019-10-19
411_18e_Report_TFR_NBA70_V1 dated 2020-02-09
411_18e_Report_TFR_S39_V1 dated 2020-02-09

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	170763735
Effective date	2020-02-09
Expiry date	2023-11-02
Frankfurt am Main	2020-02-09

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)

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:

STED_CE-Approval_Acclino flex Stent-E_A
STED_CE_Approval_Acclino flex plus Stent-E_A dated 2018-09-28
411_18e_Report_TFR_Sterilization Inpac_V1 dated 2019-09-23
STED_CE-Approval_Acclino flex plus Stent-E_B dated 2019-10-29

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

Examination report:

411_18E_Report_TFR_Acclino_V1 dated 2019-01-14
10_411_18e_Report_TFR_SterilizationInpac_V1 dated 2019-10-19
411_18e_Report_TFR_Acclino_V2 dated 2020-05-04

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	170769446
Effective date	2020-05-04
Expiry date	2024-01-13
Frankfurt am Main	2020-05-04

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
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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: 170769446
Effective date: 2020-05-04

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

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: STED_CE_Approval_NeuroSpeed-E A dated 2018-12-20

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

Examination report: 411_18e_Report_TFR_NeuroSpeed_2018_V1 dated 2019-02-16

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	170734246
Effective date	2019-05-26
Expiry date	2024-05-25
Frankfurt am Main	2019-02-16

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

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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
Accero® Rex Stent

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_Accero Stent-E_B.pdf dated 2019-06-28
STED_CE-Approval_Accero Rex Stent-E_A.pdf dated 2019-10-29

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

Examination report: 411_18e_Report_TFR_Accero_V1.docx dated 2020-01-19
411_18e_Report_TFR_Accero_V1.1.docx dated 2020-04-01

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	170769436
Effective date	2020-04-01
Expiry date	2024-05-26
Frankfurt am Main	2020-04-01

DQS Medizinprodukte GmbH

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