ENGINEERING STROKE SOLUTIONS

Summary of safety and clinical performance:

NeuroSlider® DLC

Acandis GmbH

Summary of Safety and Clinical Performance according to Medical Device Regulation (MDR) EU 2017/745

Identifier: 2200

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1 Information for the professional user

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the NeuroSlider® DLC.

The SSCP is prepared in accordance with the Medical Device Regulation (EU) 2017/745 (MDR) and the document MDCG 2019-9 of the Medical Device Coordination Group.

The SSCP is not intended to replace the instructions for use (IFU) as the main document to ensure the safe use of the NeuroSlider® DLC, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

1.1 Device identification and general information

Device trade name(s)	– **NeuroSlider® 17 DLC (DLC 1.9F)** # 01-000282 (155 cm) / # 01-000283 (160 cm) / # 01-000284 (167 cm) – **NeuroSlider® 21 DLC (DLC 2.5 F)** # 01-000292 (155 cm) / # 01-000293 (160 cm) / # 01-000294 (167 cm) – **NeuroSlider® 27 DLC pro (DLC pro 3F)** # 01-000277 (155 cm) – **NeuroSlider® 27 DLC (DLC 3F)** # 01-000276 (155 cm) – **NeuroSlider® 39 DLC (DLC 4F)** # 01-000262 (125 cm) / # 01-000263 (135 cm) / # 01-000264 (145 cm) – **NeuroSlider® 52 DLC pro (DLC pro 5F)** # 01-000261 (145 cm) / #01-000260 (135 cm) / # 01-000259 (125 cm) / # 01-000258 (115 cm) / # 01-000257 (105 cm) – **NeuroSlider® 52 DLC (DLC 5F)** # 01-000256 (145 cm) / # 01-000255 (135 cm) / # 01-000254 (125 cm) / # 01-000253 (115 cm) / # 01-000252 (105 cm)
Manufacturer's name and address	Acandis GmbH, Theodor-Fahrner-Straße 6, 75177 Pforzheim, Germany
Manufacturer's single registration number (SRN)	DE-MF-000006259
Basic UDI-DI	426065033NeuroSliderDLC7Z
Medical device nomenclature	– EMDN: C010499 (angiography and hemodynamics devices – other) – UMDNS: 17-846 (catheters, intravascular, guiding) – GMDN: 10691 (Intravascular microflow catheter)
Class of device	Class III medical device, as defined in Medical Device Regulation (MDR) EU 2017/745, Annex VIII, rule 7, bullet point 2
Year of first CE certificate	NeuroSlider® DLC was first CE-marked according to MDD in May of 2019
Authorized representative	Not applicable
Notified body	DQS Medizinprodukte GmbH (Notified body number: 0297)

1.2 Intended use of the device

Intended purpose	The NeuroSlider® DLC is intended for the controlled selective infusion of medically prescribed therapeutic or diagnostic agents and the delivery of devices (e.g. stents).
Indication(s)	The NeuroSlider® DLC is intended for the diagnostics or treatment of peripheral and cerebrovascular diseases that can be treated endovascularly.
Targeted population(s)	Intended user: Physicians who have the necessary background knowledge and the required experience in the field of interventional radiology. Patient target group: No special patient populations defined but patients with contraindications are to be excluded.
Contraindications and/or limitations	The NeuroSlider® DLC is contraindicated for patients in whom angiography reveals anatomical conditions unsuitable for endovascular treatment due to severe vessel tortuosity. The NeuroSlider® 52 DLC and the NeuroSlider® 52 DLC pro are contraindicated for patients whose vessels have a degree of stenosis higher than 80 %. General contraindications in connection with endovascular and/or angiography treatments must be taken into consideration.

1.3 Device description

1.3.1 Description of the NeuroSlider®

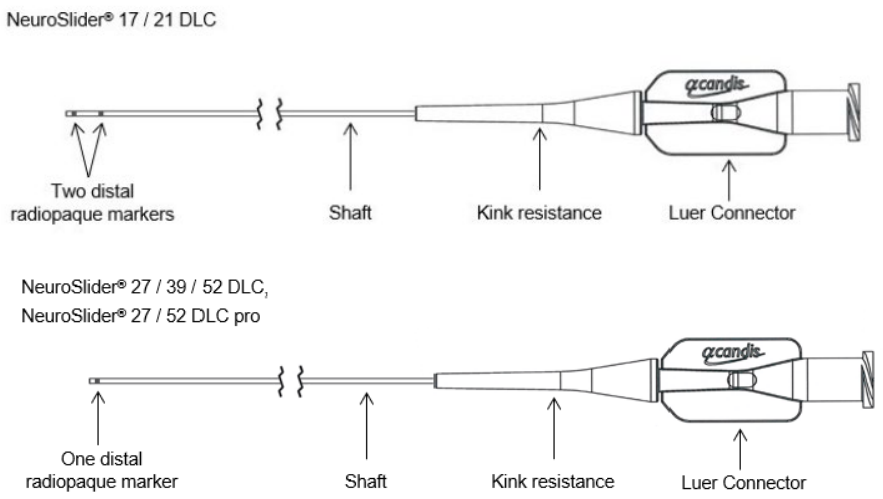
The NeuroSlider® DLC is an endhole, single lumen catheter, which is introduced into the blood vessel via a steerable delivery system. At its proximal end, the NeuroSlider® DLC is equipped with a standard Luer connector for the attachment of accessories. The rigidity of the catheter shaft decreases distally, enabling easy access of distal and tortuous vessel segments. One or two radiopaque markers on the distal end facilitate visibility under fluoroscopy. The outer surface of the catheter has a hydrophilic coating for improved lubricity. The catheter tip is shapeable. The sizes are specified on the label.

The microcatheter is provided sterile for single use only. The Acandis NeuroSlider® DLC is compatible with standard guiding catheters/sheaths and guide wires.

Application principle:

Insertion of the catheter using a suitable guide wire and appropriate accessories (such as guide catheter, sheath, hemostatic valves, infusion bags, etc.) to safely reach the target zone for controlled selective infusion of medically prescribed therapeutic or diagnostic agents and for the delivery of devices (e.g. stents).

Table 1: Characteristics of the NeuroSlider® DLC, ID: inner diameter, OD: outer diameter * The variants “pro” have a thinner liner wall thickness, resulting in a difference in catheter performance



Product Name	ID (inch)	OD dist. / prox. (French)	Usable length (cm)	Tip shape	Tip marker
NeuroSlider® 17 DLC	0.0165	1.9 / 2.3	155/160/167	Straight, shapeable	2
NeuroSlider® 21 DLC	0.021	2.3 / 2.6	155/160/167	Straight, shapeable	2
NeuroSlider® 27 DLC	0.027	3.0 / 3.1	155	Straight, shapeable	1
NeuroSlider® 27 DLC pro	0.027	3.0 / 3.1	155	Straight, shapeable	1
NeuroSlider® 39 DLC	0.039	4.0 / 4.1	125/135/145	Straight, shapeable	1
NeuroSlider® 52 DLC	0.052	5.0 / 5.1	105/115/125/135/145	Straight, shapeable	1
NeuroSlider® 52 DLC pro	0.052	5.0 / 5.1	105/115/125/135/145	Straight, shapeable	1

1.3.2 Previous generations

The first generation of the NeuroSlider® family was the NeuroSlider® 2F/2.5F/3F, initially CE-marked in July 2013, i.e. clinical experience has been gained with these products in routine use since then.

The first generation NeuroSlider® DLC has been on the market since 2019 and the second generation since May 2021. This second generation received CE mark since March 2023 under the provisions of the MDR.

1.3.3 Accessories

Tip Forming Wire (for NeuroSlider® 17 DLC, 21 DLC, 27 DLC, 27 DLC pro) / Tip Shaping Mandrel 4 F (for NeuroSlider® 39 DLC, 52 DLC and 52 DLC pro) for optional shaping of the catheter tip.

1.3.4 Combination with other devices

The NeuroSlider® DLC is intended for use in combination with:

Laser-cut and braided devices, e.g. appropriate Acandis stents (compatibility is defined on device label).

1.4 Risks and warnings

1.4.1 Residual risks and undesirable effects

According to the risk management, after risk-mitigating measures, there are no unacceptable residual risks. As adverse effects or injuries may occur peri-interventionally, Acandis specifies the following possible complications and undesirable side effects for their NeuroSlider®:

Possible complications, among others, include the following:

- General complications in connection with endovascular and/or angiographic treatments (e.g. (Pseudo)aneurysm, Rupture of or bleeding from aneurysm, (Intracerebral) haemorrhage, Embolism (air, foreign body, plaque or thrombus), Fever, (Arteriovenous) fistula, Vessel dissection, Vessel perforation, Vessel rupture, (Abrupt) vessel occlusion or thrombosis, Infection, (Cerebral) ischaemia/infarction, Secondary haemorrhage, Reactions due to radiation exposure, Subarachnoid haemorrhage, Thromboembolic event/stroke, Vasospasm)
- General complications in connection with antiplatelet agents/anticoagulants, anaesthetics and contrast agents (e.g. Renal insufficiency)
- Complications in connection with vessel entry (e.g. Haematoma or bleeding at puncture site, Pain and/or infection at puncture site)
- Possible problems during catheter delivery (e.g. Delamination or degradation of the hydrophilic coating, Catheter lumen cannot be flushed, Catheter breakage, Incorrect catheter placement, Catheter cannot be withdrawn, Catheter bending, Catheter collapses near tip, Catheter compression, Catheter damage, Particles enter the bloodstream during the intervention, Therapeutic or diagnostic aids cannot be used, Delayed treatment, Target area inaccessible or cannot be accessed safely)
- Other complications in connection with the catheter (e.g. Allergic reactions to the catheter material, Aneurysm perforation, (Distal) embolisation including previously unaffected areas, Local inflammatory reaction, Systemic immune response)
- Neurological deficits (e.g. Dysphasia, Hemiparesis, Hemiplegia, Impaired vision, Oculomotor paresis, Speech disorders)
- Death

As no complications related to the use of the NeuroSlider® (DLC) were reported by the identified and reviewed publications stating the devices' use, no quantitative data on the occurrence rate of complications with the NeuroSlider® (DLC) could be drawn (chapter 1.5.3.1). Concerning PMCF measures, clinical data on the NeuroSlider® (DLC) are collected from completed and ongoing studies (see chapter 1.5.3.2).

1.4.2 Warnings and precautions

Warnings

- The NeuroSlider® DLC should be applied only by physicians who have the necessary background knowledge and the required experience in the field of interventional radiology.
- No specific patient populations have been defined but patients with contraindications are to be excluded.
- Before use, the product needs to be carefully checked to ensure there is no transportation damage. Under no circumstances should damaged or kinked catheters be used.
- The catheter is intended for short-term use in a surgical environment for no longer than 24 hours. To prevent infections, it must be ensured that the hygiene standards are complied with and monitored throughout the entire period of use. If used for longer periods, bacterial colonisation of the catheter may occur.
- The infusion pressure must not exceed the values specified in the flow table. Exceeding these values may cause cracks/ruptures in the catheter. After using contrast agents, ensure that the catheter is adequately flushed.
- If the infusion flow is interrupted, no attempt must be made to correct this by applying a high pressure infusion. Instead, the catheter must be removed in order to determine what caused the blockage or it must be replaced by a new catheter.
- On no account whatsoever should you continue advancing the catheter if you encounter resistance without first finding out the cause as otherwise you could damage the catheter or perforate a vessel.
- Intraluminal instruments must never be moved against resistance within the catheter. The application of too much force against resistance may lead to damage (e.g. cracks/ruptures) to the instrument or injury to the vessel wall.
- Compatibility of the NeuroSlider® DLC with liquid embolisates cannot be guaranteed. It is not suitable for liquid embolisates based on cyanoacrylate and dimethyl sulphoxide (DMSO). The catheter may adhere to the embolisation material.

- The product may only be used for the intended purpose. Any use of the product for other purposes (off-label use) may lead to a deterioration in the patient's state of health or even their death

Precautions

- The product is provided sterile and for single use only.
- In case of damage to the sterile barrier or if the packaging has been opened accidentally, the product must not be used. If any damage is visible, please contact your Acandis representative.
- Do not use the product after the expiry date printed (see label).
- Do not reuse, reprocess or resterilise. Reuse, reprocessing or resterilisation may compromise structural integrity of the components and/or lead to failure that, in turn, may result in complications, patient injury or death. Reuse, reprocessing or resterilising the device also increases the risk of contamination of the device and/or causes patient infection or crossinfection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.
- The hydrophilic coating of the outer surface of the NeuroSlider® DLC must be kept hydrated to maintain its lubricious properties.
- Once the NeuroSlider® DLC is inside the body, it should only be moved under fluoroscopy. Do not remove the catheter without checking how the tip reacts.
- The manufacturers' instructions for use should be observed for all devices and substances used together with the NeuroSlider® DLC.

1.4.3 Other relevant aspects of safety

The total complaint rate and the total incident rate since first CE-approval are low with 0.21 % and 0.03 %, respectively.
The medical benefit continues to outweigh the residual risk.
There were also no relevant hits on unduly or unknown risks of the NeuroSlider® (DLC) in the databases of competent authorities.

1.5 Summary of clinical evaluation and relevant information on post-market clinical follow-up (PMCF)

1.5.1 Summary of clinical data related to equivalent devices

No clinical data from equivalent devices from other manufacturers were used for the clinical evaluation. As the variants of the NeuroSlider® (DLC) have an identical clinical application,

principle of operation and material, the clinical evaluation was conducted by pooling the clinical data of the different variants and evaluating them together.

1.5.2 Summary of clinical data from conducted investigations of the device before CE-marking

No clinical data from proprietary investigations before CE-marking are available.

1.5.3 Summary of clinical data from other sources

1.5.3.1 Clinical data in the literature

It has to be noted that publications stating the use of the NeuroSlider® are also reviewed as it is expected that for the NeuroSlider® DLC no or only very few publications will be identified within the scope of literature search. This is justified as the technical differences between NeuroSlider® and NeuroSlider® DLC are negligible and do not have an impact on their clinical application. Hence, clinical data are interchangeable i.e., clinical data on the NeuroSlider® gained from literature were also used for the evaluation of safety and performance of the NeuroSlider® DLC. The NeuroSlider® DLC is optimized for the delivery of braided stents.

Relevant clinical data on the NeuroSlider® (DLC) and thus, the NeuroSlider® DLC are sourced from published clinical references (identified by a systematic literature search in relevant electronic databases). The references for these articles can be found in the bibliography at the end of the document. For the recent CER revision 11, a total of 37 publications encompassing 15 clinical studies and 16 case series gathering real-world data on the application of mostly the NeuroSlider® in its intended use and regular clinical practice from which the safety and performance of the NeuroSlider® DLC device family can be deduced were evaluated. In the identified and reviewed clinical literature, a total of roughly 2,709 NeuroSlider® microcatheters with different inner diameters (0.017”, 0.021”, 0.027”, 0.039” and 0.052” (catheter) were used in just as many patients for the delivery of different neurovascular stents as well as other catheters or the aspiration of blood samples.
The authors did not report any performance or safety issues directly related to the use of the NeuroSlider® (DLC) microcatheters. It can thus, be stated that all NeuroSlider® (DLC) microcatheters demonstrated proper safety and performance as intended by the Acandis.

The identified and reviewed publications stating the use of NeuroSlider® are summarized in the following table (Table 2).

Table 2: Summary of clinical data from publications stating the use of NeuroSlider® (DLC). References in alphabetical order. ID, inner diameter of the used NeuroSlider® (DLC) variant

Author (et al.), Year	Patient/Device №	ID [inch]	Device-related safety/ performance statements/ issues
Almohammad M, 2025a	31/31	0.052 (DLC)	none
Almohammad M, 2025b	16/16	0.052 (DLC)	none
Beuing O, 2020	32/34	0.0165	none
Brassel F, 2016	16/16	0.0165	none
Capili F (2025)	26/26	0.0165 (DLC)	none
Daglioglu E, 2020	146/146	0.027	none
Dange NN and Roy JM, 2022	13/13	0.021/0.027	none
Dietrich P, 2020	85/48	0.0165	none
Feick J, 2023	366/366	0.0165	none
Fujimura S, 2022	23/23	0.027	none
Goertz L, 2019	59/59	0.027	none
Goertz L, 2020a	131/131	0.0165	none
Goertz L, 2020b	12/12	0.027	none
Goertz L, 2023	1/1	0.027	none
Goertz L, 2024a	26/26	0.027	none
Goertz L, 2025	<60/<60	0.027	none
Ivan VL, 2025	118/118	0.021	none
Kabbasch C, 2015	14/14	0.0165	none
Kallenberg K, 2016	119/119	0.027	none
Karhi S, 2018	199/199	0.021	none
Kaschner M, 2020	33/33	0.021	none
Kaschner MG, 2019	40/40	0.021	none
Kollikowski AM, 2020	151/151	0.021/0.027	none
Kollikowski AM, 2024	132/132	0.021/0.027	none
Kraus B, 2018	42/42	0.027	none
Latacz P, 2025	4/4	n.s. DLC	none
Ozdemir G, 2026	48/48	0.0165 / 0.021 / 0.027	none
Pflaeging M, 2021	19/19	0.0165	none
Schob S, 2026	<36/<36	0.027 / 0.039 (DLC)	none
Starke A, 2024	105/105	0.0165/0.021	none
Strinitz M, 2021	58/58	0.0165/0.021	none
Topcuoglu OM, 2018	7/7	0.027	none
Tureli D, 2016	47/47	0.0165	none
Vogt ML, 2022	298/298	0.0165/0.021	none
Weiss D, 2022	174/174	0.0165/0.021	none
Zaeske C, 2020	49/49	0.027	none
Total	**~ 2,709 / ~ 2,709**		

1.5.3.2 Clinical data obtained by clinical trials or PMCF-measures

Concerning PMCF, no clinical studies were performed with NeuroSlider® DLC as it is a state of the art device, well known to the intended user group. Conclusions on the NeuroSlider® DLC's safety and performance have been drawn from two clinical studies with other Acandis products used together with the NeuroSlider® DLC. As the DERIVO 2heal flow diverter

(REheal) and the SiREX stent (RESOLVE) is normally used together with a NeuroSlider® DLC (according to IFU), clinical data on the safety and performance of the NeuroSlider® DLC are collected in these studies.

The REheal PMCF study (NCT05543447) started in December 2022 and is a prospective, multicenter, single-arm, open-label PMCF study to systematically collect information on technical success, safety, and clinical success of treatment of intracranial aneurysms with DERIVO 2heal Embolisation Device in clinical practice. A first internal interim analysis of study data revealed that the NeuroSlider® (DLC(pro)) was used in 65 cases (NeuroSlider® 17 (n = 15), NeuroSlider® 27 (n = 13), NeuroSlider® 17 DLC (n = 9), NeuroSlider® 27 DLC (n = 10), NeuroSlider® DLC pro (n = 17). In 35 of 36 (97.2 %) cases the NeuroSlider® DLC (pro)performed satisfactorily and without complications. In one (2.8 %) case, the NeuroSlider® 27 DLC was used, high friction during transfer into microcatheter was described. The final results have not been available yet. Planned end of the trial is May 2027.

The purpose of the RESOLVE pre-CE study (NCT06726928) started in August 2025 is to assess the efficacy, safety and the clinical benefit of the SiREX stent for the treatment of disabling pulsatile tinnitus due to stenosis of lateral sinus. The study will enroll patients suffering from pulsatile tinnitus related to a lateral sinus stenosis lasting more than three months, and who want to be treated with lateral sinus stenting. The NeuroSlider® DLC is used for stent delivery. Planned end of the trial is December 2029.

1.5.3.3 Clinical data in medical device databases

The German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) database of Field Corrective Actions and the medical device registries “Manufacturer and User Facility Device Experience (MAUDE) Database” maintained by the United States’ Food and Drug Administration were searched for clinical data on

- the NeuroSlider® (DLC),
- the similar Rebar 14 / 18 / 27 (Covidien as part of Medtronic, MN, USA; former ev3 Inc., Plymouth, MN, USA) as well as
- the device group of intravascular microflow catheters (microcatheters)

The most recent search was conducted on April 1, 2026 in the BfArM and the MAUDE database. The period searched in the MAUDE database encompassed January 16, 2024 to April 7, 2025.

BfArM: No records dealing with the NeuroSlider® (DLC) and the Rebar Reinforced Micro Catheter (Covidien as part of Medtronic, MN, USA; former ev3 Inc., Plymouth, MN, USA) as representative of the device group of Intravascular microflow catheter (microcatheter) could be

retrieved from recent BfArM database research. For the device group of microcatheters no new database records could be identified in the current database search. Previous relevant hits deal with device incompatibilities, device coating damage, adhesive remains in the working channel, failed endotoxin testing and labeling issues

MAUDE: Since the previous search in April 2025 various new database entries dealing with the Rebar were added to the MAUDE database. The records on death events report that the adverse event was without identified device or use problem. Similarly, also the majority of database records reporting injuries state that adverse events were without identified device or use problem. Reported patient problems for death and injury events report already known and no undue complications.

TPLC report: The TPLC product code report for the product code KRA (i.e., catheter, continuous flush) from 2021 until the date of search i.e., April 1, 2026 revealed mostly “physical resistance / sticking” and “no clinical signs, symptoms or conditions as the most prominent device and patient problems, respectively. The TPLC product code report further revealed no device and patient problems that are not already known from the current literature. The increase in the number of reports and events over the years indicates that the device group is becoming more widely used in everyday clinical practice what is associated with a corresponding increase in the number of complications.

Conclusion: In general, the survey of the databases did not reveal any undue or so far unknown emerging device- or procedure-related risks associated with the use of the NeuroSlider® DLC, the similar Rebar 14 / 18 / 27 microcatheter or the device group of microcatheters. There is no allusion to an unfavorable risk profile of microcatheters in routine clinical use.
The NeuroSlider® DLC under evaluation and the similar Rebar 14 / 18 / 27 microcatheter (Covidien as part of Medtronic, MN, USA; former ev3 Inc., Plymouth, MN, USA) as representative of the device group of Intravascular microflow catheter (microcatheter) as well as the whole device group of microcatheters appear to be effective and safe for their intended purpose. Acandis has included the potential device- and procedure-related complications in the instructions for use of the NeuroSlider® DLC.

1.5.4 An overall summary of the clinical performance and safety

The clinical literature reflecting and summarizing the state-of-the-art in selective infusion as well as device deployment (e.g., stents, coils) into peripheral and cerebral vessels using intravascular radiological microflow catheters, publications stating the use of the NeuroSlider®

(DLC) and the similar Rebar microcatheter, together with the results from the searches in authority-maintained medical device vigilance databases as well as the data collected from PMS and PMCF on the NeuroSlider® (DLC) prove the clinical performance and safety of the NeuroSlider® DLC and the generic device group of intravascular microflow catheters in general. The diagnostics or treatment of peripheral and cerebrovascular diseases that can be treated endovascularly e.g., intracranial aneurysms and ischemic stroke, by the selective infusion as well as device deployment (e.g. stents, coils) into peripheral and cerebral vessels by intravascular microflow catheters (microcatheters) are commonly used and widely accepted clinical methods as evidenced by e.g., several international guidelines. There are studies describing different techniques for the use of microcatheters. E.g. their performance is evaluated in y-stenting as well as the rendezvous wire or kissing wire technique. They all deemed the use of microcatheters as safe and effective in various indications. Therefore, the indications, contraindications, specific clinical features as well as possible complications related to the use of the evaluated devices can assumed to be known to trained medical staff performing endovascular interventions. The reviewed clinical literature on the state-of-the-art in selective infusion as well as device deployment (e.g. stents, coils) into peripheral and cerebral vessels by intravascular microflow catheters (microcatheters) and the literature including clinical data on the use of the NeuroSlider® (DLC) provide sound evidence that by using intravascular microflow catheters in general and the NeuroSlider® DLC, in particular, successful and safe infusion of therapeutic or diagnostic agents or devices (e.g., different stents and coils) is feasible. It could be shown that the NeuroSlider® DLC meets the acceptance criteria for the performance criterion of technical success and is regarding performance a state-of-the-art device. Hence, the Acandis NeuroSlider® DLC is suitable for its intended purpose of controlled selective infusion of medically prescribed therapeutic or diagnostic agents and the delivery of devices (e.g. stents) into peripheral and cerebral vessels. Thus, it can be concluded that the NeuroSlider® DLC achieves the performances intended by Acandis and meets the requirement for performance.

Microcatheters are applied minimally invasively, circumventing the risks of open surgery. Data from clinical literature show that the use of microcatheters in the selective infusion, as well as device deployment (e.g. stents, coils) into peripheral and cerebral vessels, is a safe and method that does not pose an unduly high risk for the patient and the risk profile of intravascular microflow catheters has been thoroughly characterized. However, complications associated with the selective infusion as well as device deployment (e.g. stents, coils) into peripheral and cerebral vessels by intravascular microflow catheters (microcatheters) cannot be ruled out completely. The main risks associated with the device’s use and microcatheters in general are described in detail in the medical scientific literature on the state-of-the-art in selective infusion

as well as device deployment (e.g. stents, coils) into peripheral and cerebral vessels by intravascular microflow catheters (microcatheters), thus being known to the professional user. These potential complications identified from the clinical literature that can occur using intravascular microflow catheter encompass the general complications of cerebral embolization including hemorrhage and ischemia as well as neurological deficits including stroke and death, trapping of microcatheter, microcatheter rupture / breakage, arterial perforation/dissection/rupture, aneurysm perforation/rupture, minor complications including ematoma, pain lasting a day due to puncture site oppression and angiography-related complications (sedation/anesthesia-related risks and arterial spasm. In the evaluated literature stating the use of the NeuroSlider® (DLC), there were no reports on technical and clinical complications related to the NeuroSlider® (DLC). It could be shown that the NeuroSlider® DLC meets the acceptance criteria established for the safety parameters and is regarding safety a state-of-the-art device.

No evidence on unduly or unknown risks emanating from the NeuroSlider® DLC was identified. The risks identified within the scope of the risk management process are consistent with the risks addressed in the instructions for use and identified in the clinical literature. Warnings and contraindications, as well as complications, are addressed in the instructions for use. Moreover, the active risk management implemented by Acandis for the NeuroSlider® DLC reduced all unacceptable risks to acceptable risks and the residual risks are reduced as far as possible. In the risk management, Acandis summarized that the NeuroSlider® DLC is safe for treatment and the medical benefits outweigh the residual risk. Therefore, currently, no open questions on the safety of the NeuroSlider® DLC arise from the risk management.

Overall, it can be stated that procedural and product-specific risks, corresponding warnings and precautions are adequately provided to the professional user in order to reduce the frequency of the aforementioned potential complications. The basic design, as well as the material used for the devices, have been successfully applied for several years. The NeuroSlider® DLC was subjected to various pre-clinical and laboratory test reports e.g., biocompatibility according to (harmonized) standards with successful results. Thus, the NeuroSlider® DLC meets the requirement for safety.

According to the clinical data presented in the scientific literature, the information gained from PMS including PMCF measures as well as the risk analysis, it can be concluded that risks which may be associated with the intended use of the NeuroSlider® DLC constitute acceptable risks when weighed against the benefits to the patient. Further, it can be concluded that for patients carefully selected for this treatment, undesirable side-effects constitute an acceptable risk when weighed against the performance intended by the professional user in charge. The main risks are described and documented in detail in the scientific literature, thus being known to the trained professional user. The clinical benefit is achieved and the device-specific risks

correspond to the state-of-the-art. Therefore, by complying with all warnings and precautions, the clinical benefit continues to outweigh the residual risks and the NeuroSlider® DLC offers an acceptable benefit-risk profile and meets the requirement for the acceptability of side effects and acceptable benefit-risk profile.

The regular PMS data show very low complaint and incident rates. Since market launch, the following complications were recorded for the NeuroSlider® DLC:

- (Significant) delayed treatment: 0.20 %
- Vascular trauma: 0.003 %
- N/A (not defined yet): 0.018 %

Acandis' performance and safety-related claims concerning the NeuroSlider® DLC can be adequately justified by usability tests and PMS data.

In conclusion, the Acandis NeuroSlider® DLC could be shown to be in compliance with the considered relevant General Safety and Performance Requirements (GSPRs) as specified by the Medical Device Regulation (MDR) EU 2017/745. The safety and performance of the NeuroSlider® DLC can be confirmed.

1.5.5 Ongoing or planned post-market clinical follow-up

Conclusions on the NeuroSlider® DLC's safety and performance have been drawn from two clinical studies with other Acandis products used together with the NeuroSlider® DLC. As the DERIVO 2heal flow diverter (REheal) and the SiREX stent (RESOLVE) is normally used together with a NeuroSlider® DLC (according to IFU), clinical data on the safety and performance of the NeuroSlider® DLC are collected in these studies. The REheal PMCF study (NCT05543447) started in December 2022. The final results have not been available yet. Planned end of the trial is May 2027. The RESOLVE pre-CE study (NCT06726928) started in August 2025. Planned end of the trial is December 2029 (see also chapter 1.5.3.2).

1.6 Possible diagnostic of therapeutic alternatives

The **conventional open surgical approach** was identified as alternative to the **endovascular diagnostics or treatment** of peripheral and cerebrovascular diseases by the infusion and delivery of therapeutic agents and devices using microcatheters.

The endovascular intervention technique has gained prominence in the treatment of intracranial aneurysms due to its minimal invasiveness and shorter recovery time (Liu C et al., 2023). In case of intracranial aneurysms, for instance, this alternative is clipping that requires

craniotomy, an invasive surgery of the brain, after which a neurosurgeon embeds a clip along the aneurysm neck to block it from normal circulation. Clipping involves serious inherent risks to the patient. Also, clipping is not always feasible because of the inaccessible region of the aneurysm in the brain or patients with high risk for surgery because of age or related medical cases. Due to these limitations of clipping, endovascular treatment without open surgery has become an attractive option (Karadeli HH and Kuram E, 2023). Hybrid approaches of surgical and endovascular treatment techniques are also described (Gross BA et al., 2017).

1.7 Suggested profile and training for users

The NeuroSlider® DLC may only be used by physicians who have the necessary background knowledge and the required experience in the field of interventional radiology.

1.8 Reference to harmonized standards and common specifications

Acandis also adhered to several ISO standards and internal standards during the pre-clinical and laboratory testing of the NeuroSlider® DLC as follows.

Mnemonic	Number	Title	Revision
EN	556-1	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices	2024
EN	868-5	Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods	2018
EN	868-9	Packaging for terminally sterilized medical devices - Part 9: Uncoated nonwoven materials of polyolefines - Requirements and test methods	2018
EN ISO	10555-1	Sterile, single-use intravascular catheters - Part 1: General requirements (ISO 10555-1:2023)	2023
EN ISO	10993-23	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)	2021
EN ISO	10993-18	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020+Amd 1:2022)	2020 + A1:2023
EN ISO	10993-17	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2023)	2023
EN ISO	10993-12	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021)	2021
EN ISO	10993-11	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)	2018

Mnemonic	Number	Title	Revision
EN ISO	10993-10	Biological evaluation of medical devices - Part 10: 2023 Tests for skin sensitisation (ISO 10993-10:2021)	2023
EN ISO	10993-7	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008 + Cor 1:2009 + Amd 1:2019)	2008+AC:2009+ A1:2022
EN ISO	10993-5	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)	2009/A11:2025
EN ISO	10993-4	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017+Amd1:2025)	2017+A1:2025
EN ISO	10993-3	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)	2014
EN ISO	10993-2	Biological evaluation of medical devices – Part 2: Animal welfare requirements (ISO 10993-2:2022)	2022
EN ISO	10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2018, including corrected version 2018-10)	2020
EN ISO	11135	Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014+Amd.1:2018)	2014+A1:2019
EN ISO	11138-2	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)	2017
EN ISO	11138-1	Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2017)	2017
EN ISO	11139	Sterilization of health care products - Vocabulary of terms used in sterilization and related equipment and process standards (ISO 11139:2018+Amd 1:2024)	2018+A1:2024
EN ISO	11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2: 2019+Amd 1:2023)	2020+A 1:2023
EN ISO	11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019+Amd 1:2023)	2020+A 1:2023
EN ISO	11737-1	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018 + Amd 1:2021)	2018+A1:2021
EN ISO	11737-2	Sterilization of health care products – Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)	2020
EN ISO	13485	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	2016+AC:2018+ A11:2021

Mnemonic	Number	Title	Revision
EN ISO	14644-5	Cleanroom and associated controlled environments - Part 5: Operations (ISO 14644-5:2025)	2025
EN ISO	14644-4	Cleanroom and associated controlled environments - Part 4: Design, construction and start-up (ISO 14644-4:2022)	2022
EN ISO	14644-3	Cleanrooms and associated controlled environments - Part 3: Test methods (ISO 14644-3:2019)	2019
EN ISO	14644-2	Cleanrooms and associated controlled environments - Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration (ISO 14644-2:2015)	2015
EN ISO	14644-1	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)	2015
EN ISO	14971	Medical devices - Application of risk management to medical devices (ISO 14971:2019)	2019 + A11: 2021
EN ISO	15223-1	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)	2021
EN	17141	Cleanrooms and associated controlled environments - Biocontamination control	2020
EN ISO	20417	Medical devices – Information to be supplied by the manufacturer (ISO 20417:2021, corrected version 2021-12)	2021
EN	62366-1	Medical devices - Part 1: Application of usability engineering to medical devices (IEC 62366-1+COR1:2016+A1:2020)	2015+AC:2015+ A1:2020
EN ISO	80369-1	Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements (ISO 80369-1:2018)	2018
EN ISO	80369-7	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications (ISO 80369-7:2021)	2021
EN ISO	80369-20	Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test Methods (ISO 80369-20:2024)	2024

2 Information for the patient

This part of the SSCP is not deemed necessary for the NeuroSlider® DLC.

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