ENGINEERING STROKE SOLUTIONS

# Summary of Safety and Clinical Performance:

## NeuroSlider®

## Acandis GmbH

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

Identifier: 2201

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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.

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, 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** | |
| | Model | Article number |
| | NeuroSlider 17 | 01-000272 |
| | NeuroSlider 21 | 01-000273 |
| | NeuroSlider 27 | 01-000274 |
| **Manufacturer's name and address** | Acandis GmbH,<br>Theodor-Fahrner-Straße 6, 75177 Pforzheim, Germany | |
| **Manufacturer's single registration number (SRN)** | DE-MF-000006259 | |
| **Basic UDI-DI** | 426065033NeuroSlider93 | |
| **Medical device nomenclature** | – EMDN: C0104020 20380 (embolization devices – accessories)<br>– UMDNS: 17-846 (catheters, intravascular, guiding)<br>– 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 was first CE-marked according to MDD in 2013 | |
| **Authorized representative** | Not applicable | |
| **Notified body** | DQS Medizinprodukte GmbH (Notified body number: 0297) | |

## 1.2 Intended use of the device

| | |
|---|---|
| **Intended purpose** | The NeuroSlider 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 is intended for the diagnostics or treatment of peripheral and cerebrovascular diseases that can be treated endovascularly. |

| | |
|---|---|
| **Targeted population(s)** | – Intended user: The NeuroSlider may only be used by physicians who have the required background knowledge in the field of interventional radiology.<br>– Patient target group: No special patient populations defined but patients with contraindications are to be excluded |
| **Contraindications and/or limitations** | The NeuroSlider is contraindicated for patients who present in the angiography with anatomical conditions unsuitable for endovascular treatment due to severe vessel tortuosity. General contraindications in connection with endovascular and/or angiographic treatments must be taken into consideration |

## 1.3 Device description

### 1.3.1 Description of the NeuroSlider

The NeuroSlider is a single-lumen, distally open microcatheter, which is inserted into the blood vessels using a controllable delivery system. At its proximal end, the NeuroSlider is equipped with a standard Luer connection for attaching accessories. The rigidity of the microcatheter shaft decreases in a distal direction, thus making it possible to easily reach distal and tortuous vessel sections. One or two x-ray markers at the distal end increase visibility during fluoroscopy, see Table 1.

The outer surface of the microcatheter has a hydrophilic coating for improved lubricity. The microcatheter tip can be shaped. The sizes are specified on the label.

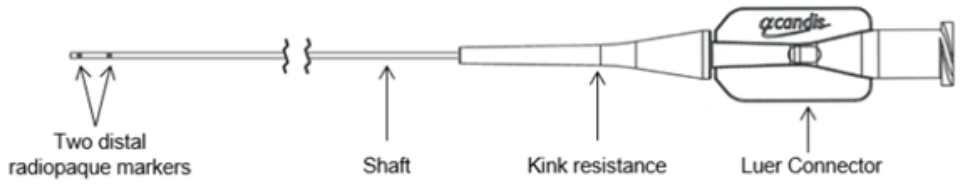
There is no hydrophilic coating at the very proximal end to facilitate handling.

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

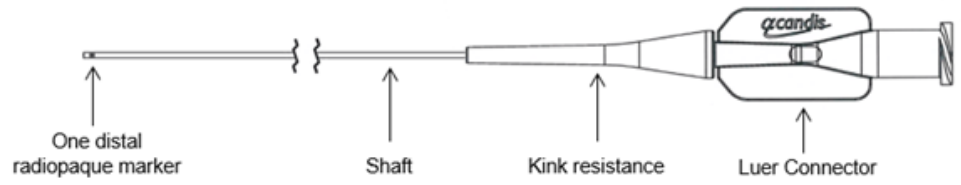
*Application principle*

Insertion of the microcatheter 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 Acandis NeuroSlider




Microcatheter Design for NeuroSlider® 17 and 21




Microcatheter Design for NeuroSlider® 27

| | ID (inch) | OD dist. / prox. (French) | Usable length (cm) | Tip shape | Tip marker |
|---|---|---|---|---|---|
| NeuroSlider 17 | 0.0165 | 1.9 / 2.1 | 155 | Straight (shapeable) | 2 |
| NeuroSlider 21 | 0.021 | 2.4 / 2.5 | 155 | Straight (shapeable) | 2 |
| NeuroSlider 27 | 0.027 | 3.0 / 3.1 | 155 | Straight (shapeable) | 1 |

### 1.3.2 Previous generations

The previous generation of the NeuroSlider was the NeuroSlider 2F/2.5F/3F, first CE approval according to MDD in July 2013.

### 1.3.3 Accessories

Guide wire, RHV (rotating hemostatic valve), syringe, tip shaping mandrel, guiding catheter/sheath.

If shaping of the catheter tip desired, shaping is possible by the use of steam and tip shaping mandrel.

### 1.3.4 Combination with other devices

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. Rupture of or bleeding from aneurysm, (Intracerebral) hemorrhage, Embolism (air, foreign body, plaque or thrombus), Fever, Vessel dissection, Vessel perforation, Vessel rupture, Infection, (Cerebral) ischemia/infarction, Secondary hemorrhage, Reactions due to radiation exposure, Subarachnoid hemorrhage, Thromboembolic event/stroke, Vasospasm, Intoxication)
- General complications in connection with thrombocyte aggregation inhibitors/anticoagulants, anesthetics and contrast agents (e.g. Renal insufficiency)
- Complications in connection with vessel entry (e.g. Hematoma or bleeding at puncture site, Pain and/or infection at puncture site)
- Possible problems during catheter delivery (e.g. Catheter breakage, Incorrect catheter placement, Catheter cannot be withdrawn, Catheter bending, Catheter compression, Catheter damage, 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)
- Neurological deficits (e.g. Dysphasia, Hemiparesis, Hemiplegia, Impaired vision, Oculomotor paresis, Speech disorders)
- Death

As no complications were reported by the identified and reviewed publications stating the use of the NeuroSlider, no quantitative data on the occurrence of complications with the NeuroSlider could be drawn (chapter 1.5.3.1). From a PMCF measure with evaluation sheets in 2015, no information on complications were assessed. So far, there are no results from the ongoing PMCF studies HYBRID, REVISAR and REheal yet from which quantitative data on complications related to the NeuroSlider could possibly derived. First results are expected in the middle of 2023 (chapter 1.5.3.2).

### 1.4.2 Warnings and precautions

*Warnings*

- The NeuroSlider may only be used by physicians who have the required background knowledge and experience in the field of interventional radiology.
- No specific patient populations have been defined but patients with contraindications (see chapter 1.2) 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 microcatheters be used.
- The microcatheter 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 colonization of the microcatheter may occur.
- The infusion pressure must not exceed the values given in the flow table in the IFU. Exceeding these values may cause cracks/ruptures in the microcatheter. After using contrast agents, ensure that the microcatheter 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 microcatheter must be removed in order to determine what caused the blockage or it must be replaced by a new microcatheter.
- Intraluminal instruments must never be moved against resistance within the microcatheter. 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 with liquid embolizates cannot be guaranteed. It is not suitable for liquid embolizates based on cyanoacrylate and dimethyl sulfoxide (DMSO). The microcatheter may adhere to the embolization 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, the product must not be used. If any damage is visible, please contact your Acandis representative.
- Do not use the product after the expiration date printed on the label.
- Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise structural integrity of the device and/or lead to device failure that, in turn, may result in complications, patient injury or death. Reuse, reprocessing or resterilizing

the device also increases the risk of contamination of the device and/or causes patient infection or cross-infection, 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 must be kept hydrated to maintain its lubricious properties.
- Once the NeuroSlider is inside in the body, it should only be moved under fluoroscopy. Do not remove the microcatheter without checking how the tip reacts.
- The manufacturers' instructions for use should be observed for all devices and substances used together with the NeuroSlider.

### 1.4.3 Other relevant aspects of safety

The total complaint rate is 0.20 %, and the total incident rate is 0 % (July 2018 – June 2022). The medical benefit continues to outweigh the residual risk. There were also no relevant hits on unduly or unknown risks of the NeuroSlider 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 of equivalent devices from other manufacturers were used for the clinical evaluation. As the variants of the NeuroSlider 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

Relevant clinical data on the NeuroSlider 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 clinical evaluation report, ten clinical studies and thirteen case series - from which the safety and

performance of the NeuroSlider can be deduced - were evaluated. In the reviewed clinical literature, a total of roughly 1,735 NeuroSlider microcatheters with different inner diameters (0.017”, 0.021”, 0.027” – all available device variants are covered) were used in just as many patients for the delivery of different neurovascular stents as well as other catheters. The authors did not report any performance or safety issues related to the use of the NeuroSlider microcatheter. It can thus, be stated that all NeuroSlider microcatheters demonstrated the safety and performance as intended by the Acandis.

The identified publications stating the use of NeuroSlider are summarized in the following Table 2. The references can be found in the bibliography (chapter 3).

Table 2: Summary of clinical data on publications stating the use of NeuroSlider. n.a.: not applicable; n.d. not deducible, n.s.: not specified, due to the information given in the publication, the clinical data could not be clearly assigned to a specific prosthesis variant. References in alphabetical order.

| Author (et al.), Year | Patient/Device № | Inner diameter [inches] | Safety/ performance statements/issues |
|---|---|---|---|
| Beuing O 2020 | 32/34 | 17 | none |
| Brassel F 2016 | 16/16 | 17 | none |
| Daglioglu E 2020 | 146/146 | 27 | none |
| Dange NN and Roy JM 2022 | 13/13 | 21/27 | none |
| Dietrich P 2020 | 85/48 | 17 | none |
| Fujimura S 2022 | 23/23 | 27 | none |
| Goertz L 2019 | 59/59 | 27 | none |
| Goertz L 2020a | 131/131 | 17 | none |
| Goertz L 2020b | 12/12 | 27 | none |
| Kabbasch C 2015 | 14/14 | 17 | none |
| Kallenberg K 2016 | 119/119 | 27 | none |
| Karhi S 2018 | 199/199 | 21 | none |
| Kaschner M 2020 | 33/33 | 21 | none |
| Kaschner MG 2019 | 40/40 | 21 | none |
| Kollikowski AM 2020 | 151/151 | 21/27 | none |
| Kraus B 2018 | 42/42 | 27 | none |
| Pflaeging M 2021 | 19/19 | 17 | none |
| Strinitz M 2021 | 58/58 | 17/21 | none |
| Topcuoglu OM 2018 | 7/7 | 27 | none |
| Tureli D 2016 | 47/47 | 17 | none |
| Vogt ML 2022 | 298/298 | 17/21 | none |
| Weiss D 2022 | 174/174 | 17/21 | none |
| Zaeske C 2020 | 49/49 | 27 | none |
| **Total** | **1,735 / 1,735** | | |

### 1.5.3.2 Clinical data obtained by clinical trials or PMCF-measures

A summary of user experience with the NeuroSlider after 12 recanalization procedures is depicted in Table 3. The NeuroSlider was used for the treatment of thromboses, stenoses, aneurysms and other conditions.

Table 3: Assessment of catheter properties in January 2015

| Property | Assessment (%) | | | | |
|---|---|---|---|---|---|
| | very good | good | neutral | poor | very poor |
| Ease of preparation | 64 | 36 | 0 | 0 | 0 |
| Trackability | 55 | 36 | 9 | 0 | 0 |
| Flexibility | 50 | 33 | 0 | 8 | 8 |
| Torquability. | 11 | 56 | 22 | 0 | 11 |
| Positioning | 50 | 33 | 8 | 0 | 8 |
| Visibility X-ray markers | 42 | 50 | 8 | 0 | 0 |
| Visibility shaft | 0 | 70 | 30 | 0 | 0 |

#### 1.5.3.3 Clinical data in medical device databases

The medical device registries “Manufacturer and User Facility Device Experience (MAUDE) Database” maintained by the United States’ Food and Drug Administration as well as the German Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) database of Field Corrective Actions were searched for clinical data on the NeuroSlider during the preparation of the CER. The recent search was conducted on December 14, 2022 and the searched time period in the MAUDE database encompassed October 01, 2021 to December 10, 2022.

The searches in the BfArM database did not yield any records regarding deaths caused by the Acandis NeuroSlider and the similar Rebar 14 / 18 / 27 microcatheter (Covidien as part of Medtronic, MN, USA; former ev3 Inc., Plymouth, MN, USA)

The searches in the MAUDE database revealed several entries about the Rebar with already known potential complications. It has to be noticed that the vast majority of the records from Nov 2020 to December 2022 are no device- or procedure-related complications.

### 1.5.4 An overall summary of the clinical performance and safety

The clinical literature reflecting the state-of-the-art in the 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 and the similar Rebar microcatheter, together with the results from the searches in authority-maintained vigilance databases as well as the data collected from PMS and PMCF measures on the NeuroSlider prove the clinical performance and safety of the NeuroSlider and the generic product group of intravascular microflow catheters in general. Studies provide sound evidence that by using intravascular microflow catheters in general and the NeuroSlider microcatheter, in particular, successful and safe infusion of therapeutic or diagnostic agents or devices (e.g.,

different stents and coils) is feasible. Therefore, the Acandis NeuroSlider is suitable for its intended use. Thus, it can be concluded that the NeuroSlider achieves the performances intended by Acandis and meets the requirement for performance.

The main risks related to the use of intravascular microflow catheters and, thus, the NeuroSlider are described and documented in detail in the scientific literature, thus being known to the professional user. The 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, bacterial colonization, 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) which all cannot be ruled out completely.
No evidence on unduly or unknown risks of the NeuroSlider was identified. The risks identified within the scope of the risk management process are consistent with the risks addressed in IFU and identified in the clinical literature. 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.
In the evaluated literature, there were no reports on technical and clinical complications related to the NeuroSlider. The basic design, as well as the material used for the devices, have been successfully applied for several years. The NeuroSlider was subjected to various pre-clinical and laboratory test reports e.g., biocompatibility according to (harmonized) standards with successful results. Thus, the NeuroSlider meets the requirement for safety.

According to the clinical data presented in the scientific literature, the information gained from PMS and 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 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 trained professional user. Therefore, by complying with all warnings and precautions, the NeuroSlider offers an acceptable benefit-risk profile and meets the requirement for an acceptability of side effects and acceptable benefit-risk profile.

The regular PMS data show very low complaint rates.

Acandis' clinically relevant marketing claims related to safety and performance concerning the NeuroSlider can be adequately justified by the device's technical properties, Acandis' product testing as well as PMS data.

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

### 1.5.5 Ongoing or planned post-market clinical follow-up

Clinical data of the NeuroSlider will be collected from ongoing studies of other Acandis products used together with the NeuroSlider.

- In the Hybrid and REVISAR thrombectomy studies (with the Acandis product APERIO Thrombectomy Device), all adverse events to the intervention are recorded. As the stent retriever is normally is used together with a NeuroSlider microcatheter (according to IFU), clinical data on the safety and performance of the NeuroSlider are also collected in these studies.
- Additionally, clinical data on NeuroSlider will be collected in the ongoing DERIVO 2heal Study REheal (compatibility of DERIVO 2heal and NeuroSlider as per IFU).

There are no results from the ongoing PMCF studies HYBRID, REVISAR and REheal yet. First results are expected in the middle of 2023 (personal information Acandis, March 2023)

## 1.6 Therapeutic alternatives for endovascular treatments using micro-/catheters

Identified alternatives to endovascular treatment using microcatheters for the infusion and delivery of therapeutic agents and devices, respectively, is the conventional surgical approach by open surgery applying e.g. craniotomy and clipping of the aneurysm (Armoiry X et al., 2012).

## 1.7 Suggested profile and training for users

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

## 1.8 Reference to harmonized standards and common specifications

| 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 | 2001+AC:2006 |
| EN | 868-2 | Packaging for terminally sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods | 2017 |
| EN ISO | 10555-1 | Sterile, single-use intravascular catheters - Part 1: General requirements (ISO 10555-1:2013 + Amd 1:2017) | 2013+A1:2017 |
| 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) | 2020 |
| EN ISO | 10993-17 | Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002) | 2009 |
| 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 |
| 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 |
| EN ISO | 10993-4 | Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017) | 2017 |
| 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 |

| Mnemonic | Number | Title | Revision |
|---|---|---|---|
| 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) | 2018 |
| EN ISO | 11607-2 | Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019) | 2020/A11.2022 |
| 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) | 2020 / A11:2022 |
| 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 | 13485 | Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) | 2016+AC:2018+ A11:2021 |
| EN ISO | 14644-5 | Cleanroom and associated controlled environments - Part 5: Operations (ISO 14644-5:2004) | 2004 |
| EN ISO | 14644-4 | Cleanroom and associated controlled environments - Part 4: Design, construction and start-up (ISO 14644-4:2001) | 2001 |
| 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 |
| ISO | 14698-2 | Cleanrooms and associated controlled environments — Biocontamination control — Part 2: Evaluation and interpretation of biocontamination data TECHNICAL CORRIGENDUM 1 | 2003/Cor. 1:2004 |
| ISO | 14698-1 | Cleanroom and associated controlled environments - Biocontamination control - Part 1: General principles and methods | 2003 |
| 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 | 80369-7 | Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications (ISO 80369-7:2021) | 2021 |

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

## 2 Information for the patient

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

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