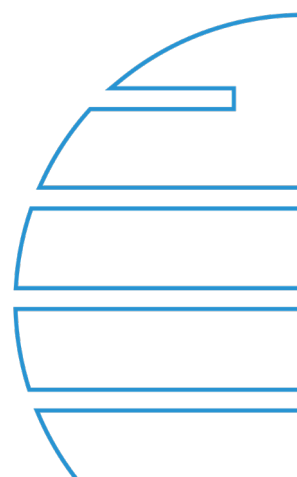
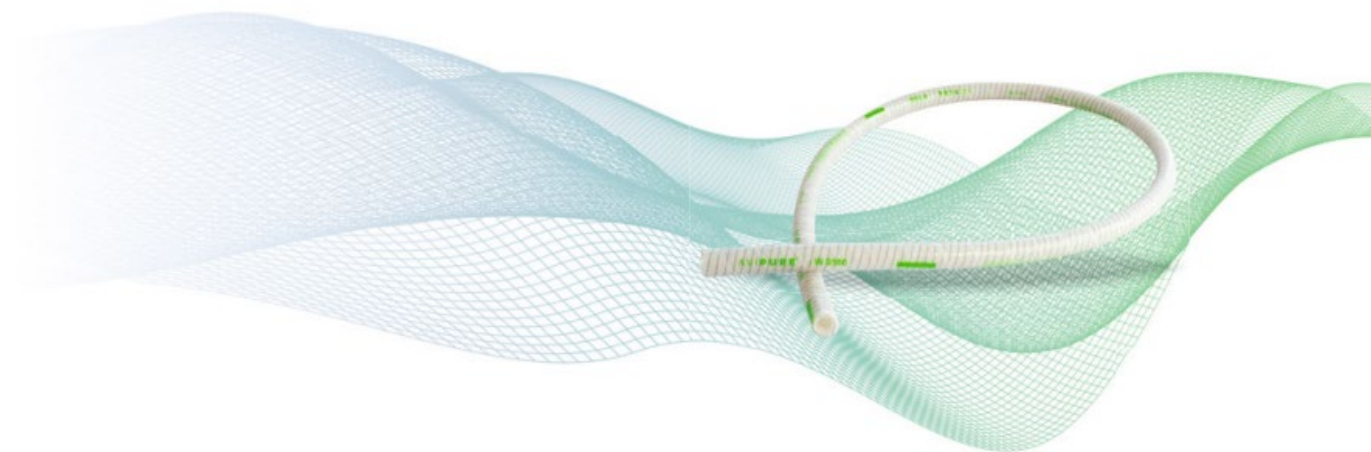


**IDEEN FÜR IHREN ERFOLG.**

LÖSUNGEN FÜR DIE PROZESS-  
UND LIFE SCIENCE INDUSTRIE



## AVIPURE® – W Certification Package



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## **1 Introduction**

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### **1.1 Development and Production of AVIPURE®-W**

avintos AG specified the technical requirements for their AVIPURE®-W (Wire-reinforced, platinum cured silicone hose) and has them manufactured through their partner TUBIGOMMA DEREGBUS S.r.l., 35030 Saccolongo PD, Italy.

AVIPURE® is a registered Trademark of avintos AG.

### **1.2 About TUBIGOMMA DEREGBUS (TUDERTECHNICA)**

TUDERTECHNICA is a privately-owned Company founded in 1983 that offers to the clients a modern, efficient manufacturing facility and a qualified and experienced staff, for the purpose of creating original customized products that meet the requests from the international market.

TUDERTECHNICA designs and manufactures specialty technical hoses for a wide range of applications in the food, chemical, petrochemical, pharmaceutical, cosmetic and for other industries requiring high performance hoses. They operate in a modern and efficient manufacturing plant employing the rigid mandrel production process.

### **1.3 Cleanroom production**

AVIPURE®-W (Wire-reinforced, platinum cured silicone hose) are manufactured, tested, and packed in a controlled environment, according to ISO 14644 class 8.

Consistent high quality of silicone hose is assured by careful selection of the raw material, well planned and validated production technologies, and an efficient Quality Assurance Department, all of which result in high batch-to-batch reproducibility.

### **1.4 Quality Management System**

TUDERTECHNICA is certified according to ISO 9001:2015 and ISO 45001:2018.

avintos is certified according to ISO 9001:2015.

You may download the certificates from the respective websites.

## 2 Technical Specifications

### 2.1 Hose Dimensions, Type and Part Numbers Overview

Hose coils made of silicone compound 81315 are manufactured in several dimensions.

The color of the hose is natural without addition of color pigments.

All hose coils are provided in double PE bags packaged in a cardboard box.

Further dimensions upon request.

| TYPE            | ID x OD<br>DIMENSIONS | HOSE<br>COIL LENGTH | WEIGHT      | ARTICLE-NUMBER |
|-----------------|-----------------------|---------------------|-------------|----------------|
| <b>AVIPURE®</b> | <b>MM</b>             | <b>M</b>            | <b>KG/M</b> |                |
| W 500           | 13 x 24               | 10                  | 0.4         | 407HSW0500-10  |
| W 750           | 19 x 30               | 10                  | 0.6         | 407HSW0750-10  |
| W 1000          | 25 x 36               | 10                  | 0.7         | 407HSW1000-10  |
| W 1250          | 32 x 43               | 10                  | 0.9         | 407HSW1250-10  |
| W 1500          | 38 x 51               | 10                  | 1.2         | 407HSW1500-10  |
| W 2000          | 51 x 64               | 10                  | 1.6         | 407HSW2000-10  |

| TYPE            | ID x OD<br>DIMENSIONS | HOSE<br>COIL LENGTH | WEIGHT        | ARTICLE-NUMBER |
|-----------------|-----------------------|---------------------|---------------|----------------|
| <b>AVIPURE®</b> | <b>INCH</b>           | <b>FT</b>           | <b>LBS/FT</b> |                |
| W 500           | 0.5 x 0.94            | 32.8                | 0.28          | 407HSW0500-10  |
| W 750           | 0.75 x 1.18           | 32.8                | 0.38          | 407HSW0750-10  |
| W 1000          | 1.0 x 1.42            | 32.8                | 0.48          | 407HSW1000-10  |
| W 1250          | 1.25 x 1.69           | 32.8                | 0.56          | 407HSW1250-10  |
| W 1500          | 1.5 x 2.0             | 32.8                | 0.81          | 407HSW1500-10  |
| W 2000          | 2.0 x 2.52            | 32.8                | 1.04          | 407HSW2000-10  |

### 2.2 Material Information

AVIPURE®-W silicone pharma hose is made of the material grade silicone compound 81315, an extruded platinum-cured silicone, translucent. Raw material tested according to the main requirements of the following norms: USP class VI; ISO 10993; European Pharmacopoeia 3.1.9. Raw material meets the requirements of 1907/2006/CE (REACH) and FDA CFR 21 177.2600

Reinforcement is made of high temperature resistant textiles, shiny stainless-steel wire helix

Cover is an extruded smooth, platinum-cured silicone, translucent, glossy.

Heat, ageing, ozone and abrasion resistant.

## 2.3 Material Compliance

The silicone inliner of the hose is compliant to:

- GMP - Reg. (CE) 2023/2006 and subsequent modifications and integrations.
- EU 10\_2011 and FDA CFR 21 177.2600  
Accredia Test report No 19-FC02691 July 20<sup>th</sup>, 2020
- 1907/2006/CE (REACH);
- ISO 10993 – 4:2017, 5:2009; 12:2012;
- USP CLASS VI MAIN REQUIREMENTS  
Biochem Test report No 19-1520-16 June 3<sup>rd</sup>, 2020;
- EUROPEAN PHARMACOPOEIA 8.1/2014 3.1.9;
- 3A Sanitary Standard 18-03-Class I.

Furthermore, the products are:

- Ethylene Oxide Sterilization compatible
- TSE/BSE free

This statement is valid until revoked or until new information is provided.  
If you require further information, please contact your responsible sales contact.

## 2.4 Physical Properties

The physical properties of the raw material were determined on standard test specimen. The specified values represent guide values.

| PROPERTY                           | NORM             | SILICONE compound 81315 |
|------------------------------------|------------------|-------------------------|
| Shore hardness A                   | ISO 48-4         | 63 ± 5                  |
| Density (g/cm <sup>3</sup> )       | ISO 1183         | 1.15                    |
| Tear strength (MPa)                | ISO 527          | ≥ 8.0                   |
| Elongation at break (%)            | ISO 527          | ≥ 500                   |
| Compression Set (% , 22h / 175 °C) | ISO 815-1 type B | ≤ 15 %                  |

## 2.5 Physico-Chemical Properties

### 2.5.1 European Pharmacopoeia: 3.1.9 & FDA regulation 21CFR, § 177.2600.

#### Test results

The silicone pharma hose compound 81315 meets the requirements of regulation 21 CFR, § 177.2600, Reg. EU10/2011, BfR XV. The test methods, limits and results are those described in separate Report No: 19-FC02691.

## 2.6 Biocompatibility

Samples of the silicone pharma hose compound 81315 were tested in accordance with the below mentioned standards to assess state-of-the-art biocompatibility requirements. This includes ISO 10993 testing as well as USP class VI tests to evaluate toxicity systemically, intracutaneously, and through implantation.

| TESTING                                                 | STANDARD                                | RESULT                                                           |
|---------------------------------------------------------|-----------------------------------------|------------------------------------------------------------------|
| Hemolysis                                               | ISO 10993-4<br>ISO 10993-12             | Pass<br>Test Report N° 19-1520-08                                |
| In-vitro Cytotoxicity                                   | ISO 10993-12<br>ISO 10993-5<br>USP <87> | Pass<br>Test Report N° 19-1520-06 &<br>Test Report N° 19-1520-07 |
| USP Class VI<br>Intracutaneous Reactivity in the rabbit | USP <88>                                | Pass<br>Test Report N° 19-1520-03                                |
| USP Class VI<br>Systemic Toxicity in the mouse          | USP <88><br>ISO 10993-11                | Pass<br>Test Report N° 19-1520-04                                |
| USP Class VI<br>Implantation muscle in the rabbit       | USP <88>                                | Pass<br>Test Report N° 19-1520-05                                |

**Note:**

AVIPURE®-W hoses are not intended for use as an implant material. Not suitable for blood or human fluids.

## 2.7 Hose Printing

The silicone pharma hose compound 81315 is marked through a Lay line with the AVIPURE®-logo, size, lot number and manufacture date.

## 2.8 Extractable Profile

Extraction and analysis for silicone pharma hose compound 81315 were conducted following Chemic R&D Study Plan 11109B, Extractable Assessment of Silicone Hose, released on April 21st, 2021.

The test materials were subjected to extraction in various solvents at controlled temperatures.

| Solvent   | Volume | Time Intervals & Conditions |
|-----------|--------|-----------------------------|
| 100% EtOH | ~40mL  | 1 day, 50 rpm at 40°C       |

The solvent extracts were then assayed according.

| Solvent   | HPLC-DAD/MS |            | DI-GC/MS | HS-GC/MS |
|-----------|-------------|------------|----------|----------|
|           | ESI (+/-)   | APCI (+/-) |          |          |
| 100% EtOH | Yes         | Yes        | Yes      | Yes      |

## 2.9 Sterilization Compatibility

It is the responsibility of the user to validate a sterilization process with autoclave for silicone pharma hose. Silicone pharma hose compound 81315 is produced for multiple use. The product will be delivered non-sterile.

Sterilization with steam (autoclave or inline sterilization SIP up to 135 °C) is generally recommended. The suitability of the material must be evaluated by the user. Possible material damage depends on the sterilization conditions (temperature, pressure, and time).

Sterilization of silicone pharma hose with multiple CIP/SIP-cycles at 135 °C does not impair fit, form or function of the products. The amount of the repetitions and the process conditions used are within the validation responsibility of the user. The user is obliged to examine the re-sterilizability under application-related conditions, since the number of resterilization cycles may be influenced by the flow medium/ cleaning agent and/ or mechanical stress applied throughout application lifetime. However, avintos has tested 300 sterilization cycles at 135°C without any visual impact on the tested hoses.

## 2.10 General Properties, Shelf Life and Storage

According to the current state-of-the-art individual fisheyes due to raw material and processing, foreign material, dirt inclusions and air bubbles as well as contamination on the hose surface, like intrinsic particles and fluff, cannot be completely excluded.

The following shelf life is valid for the non-sterile, originally packed products.

A slight discoloration of the material might appear over storage time which may vary from batch to batch in intensity. This material related aging effect is common and does neither affect functionality nor material properties of silicone pharma hose compound 81315 in the scope of specified physical properties as well as shelf-life.

The shelf life of the silicone pharma hose compound 81315 in non-sterile condition and originally packed is 5 years. There is no substantial change of the specified physical, chemical, and physiological parameters of the hose material after that period of time.

The following storage conditions shall apply:

- Storage in original packaging
- Dry (Standard conditions 10 – 75% relative humidity)
- Temperature 15 - 25°C with short-term deviations 5 – 35°C
- Goods protected from moisture
- Goods protected from directly exposure to UV-light
- Not in the environment and in presence of chemicals, e.g. solvent and disinfectant

### 3 Functional Tests

#### 3.1 Pressure Testing

The pressure ratings represent typical reference values for selected dimensions. The tests were conducted on a test bench in accordance with ISO 1402 at ambient conditions. The values are applicable for non-sterile hose.

| TYPE            | ID x OD<br>DIMENSIONS | VACUUM     | WORKING<br>PRESSURE<br>AT 20°C | MINIMUM<br>BURST<br>PRESSURE<br>AT 20°C | MINIMUM<br>BEND<br>RADIUS | ARTICLE-NUMBER |
|-----------------|-----------------------|------------|--------------------------------|-----------------------------------------|---------------------------|----------------|
| <b>AVIPURE®</b> | <b>MM</b>             | <b>BAR</b> | <b>BAR</b>                     | <b>BAR</b>                              | <b>MM</b>                 |                |
| W 500           | 13 x 24               | 0.9        | 13                             | 52                                      | 50                        | 407HSW0500-10  |
| W 750           | 19 x 30               | 0.9        | 11                             | 44                                      | 70                        | 407HSW0750-10  |
| W 1000          | 25 x 36               | 0.9        | 10                             | 40                                      | 90                        | 407HSW1000-10  |
| W 1250          | 32 x 43               | 0.9        | 8                              | 32                                      | 115                       | 407HSW1250-10  |
| W 1500          | 38 x 51               | 0.9        | 7                              | 28                                      | 140                       | 407HSW1500-10  |
| W 2000          | 51 x 64               | 0.9        | 6                              | 24                                      | 190                       | 407HSW2000-10  |

| TYPE            | ID x OD<br>DIMENSIONS | VACUUM     | WORKING<br>PRESSURE<br>AT 68°F | MINIMUM<br>BURST<br>PRESSURE<br>AT 68°F | MINIMUM<br>BEND<br>RADIUS | ARTICLE-NUMBER |
|-----------------|-----------------------|------------|--------------------------------|-----------------------------------------|---------------------------|----------------|
| <b>AVIPURE®</b> | <b>INCH</b>           | <b>PSI</b> | <b>PSI</b>                     | <b>PSI</b>                              | <b>INCH</b>               |                |
| W 500           | 0.5 x 0.94            | 13         | 188                            | 780                                     | 2.0                       | 407HSW0500-10  |
| W 750           | 0.75 x 1.18           | 13         | 160                            | 660                                     | 2.8                       | 407HSW0750-10  |
| W 1000          | 1.0 x 1.42            | 13         | 145                            | 600                                     | 3.6                       | 407HSW1000-10  |
| W 1250          | 1.25 x 1.69           | 13         | 116                            | 480                                     | 4.6                       | 407HSW1250-10  |
| W 1500          | 1.5 x 2.0             | 13         | 102                            | 420                                     | 5.5                       | 407HSW1500-10  |
| W 2000          | 2.0 x 2.52            | 13         | 88                             | 360                                     | 7.5                       | 407HSW2000-10  |

#### Remarks:

- The bursting pressure of the AVIPURE® - W hose is reduced by around 20% per temperature increase of 93°C until the maximum hose temperature is reached. The reduction is linear
- Pressure limit rates can be limited by used end connections
- Norm: ISO 1307 for dimensional tolerances
- Technical contents are subject to change with revision but without prior notice