

PRESSURE TEST CERTIFICATE & CERTIFICATES OF CONFORMANCE

For: Aflex PTFE Hose, supplied as Loose Hose or as Hose Assemblies and Loose Fittings

CERTIFICATE NO: AFH/842/202121/001

DESPATCH DATE:

22 Nov 2019

MANUFACTURING DATE: Q4/2019

ORDER DETAILS: Customer: HUBER S.A.

Customer Order No: H.2018/19

Aflex Order No: 187437 / 1 Aflex Despatch Note No: 202121

PRODUCT SUPPLIED (Loose or Assembled)

Product Type and Grade: 1" CORROFLON GP,SS

EC

Quantity and Units: 2 OFF

HOSE ASSEMBLIES ONLY

End (1): 1.00 PN40 SWIVEL FLANGE, PTFE LINED, 1.4404, L/F

End (2): 1.00 PN40 SWIVEL FLANGE, PTFE LINED, 1.4404, L/F

Hose Assembly Length: 1.000

Aflex Hose Serial No (s): 613794 613795

Customer Tag No (s):

PRESSURE TEST CERTIFICATE (Hose Assemblies Only)

This is to certify that the Hose Assemblies supplied were *all pressure tested using re-circulated, UV Filtered, deionised water, in accordance with BS EN 1402:2009 clause 8.1 "Proof Hold Test", and that the Hose Assemblies all passed this test without leakage, cracking, abrupt distortion, or other signs of failure.

Test Pressure (bar): 46.50

(Applied for at least 1 minute)

*Note: Smoothbore hose assemblies supplied in quantities more than 10, only 10% are pressure tested

CERTIFICATE OF CONFORMANCE

CERTIFICATE OF CONFORMANCE

This is to certify that the product(s) supplied have been manufactured and tested in accordance with the requirements of the Customer Order, and conform to these requirements This is to certify that the product (s) were also manufactured in accordance with Affex Hose Manufacturing, Inspection and Test Procedures, in accordance with Affex Hose BS-EN ISO 9001:2015 and IATF 16949:2015 Quality Management Systems, audited and certified by BSI.

CERTIFICATE OF CONFORMANCE to INTERNATIONAL STANDARDS

This is to certify that the Hose (s) supplied, as identified above, conform to the relevant requirements of the International Standards as specified below:

APPLICABLE TO: ALL HOSE TYPES, relevant to: THE PTFE LINER TUBES

• FDA 21 CFR 177.1550
The PTFE material used to manufacture all the PTFE liner tubes, both natural and AS (Antistatic) grades, conforms to the FDA requirements of 21 CFR 177.1550

• FDA 21 CFR 178.3297 and EN 16643 (AS Grades only)
The Antistatic (AS Grade) PTFE Liner tubes for all hose products conform to the requirements of 21 CFR 178.3297 and EN 16643, requiring that the carbon black additive is high purity furnace black, less than 2.5% by weight.

AS Grade Liner tubes also conform to the requirements of EN 16643, requiring an electrical resistance between the hose liner and an end fitting of between 103 and 108 ohms.

3-A Sanitary Standards
 The PTFE material used to manufacture the PTFE liner tubes conforms to the requirements of the 3-A Sanitary Standards.

SAE J 1737 (Automotive Fuel Hose)

Natural and Antistatic PTFE lined hose products have been tested, and conformed to the automotive fuel diffusion requirement of SAE J1737.

Reach/RoHS

We declare that to the best of our knowledge the articles we provide in the form of PTFE Flexible Hose and Hose Assemblies are compliant to restrictions listed in the SVHC Candidate list.

ASME BPE

We confirm that the PTFE hose liners are manufactured from PTFE polymer which complies with the Material of Construction requirements of ASME BPE.

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MATERIAL CERTIFICATION TO EN10204-3.1

Separately available upon request for the Components supplied

Warranty Period
 Aflex Hose Ltd warrants its products to be free from faulty materials or manufacturing defects from the date of the initial sale, for 24 months

STORAGE PERIODS FOR AFLEX PRODUCTS

The storage periods quoted assume that all components are stored in a manner to optimise the storage periods as stated in BS ISO 2230:2002 clause 6, 6.1 to 6.2.13

Storage Life by Material:
Indefinite Life (more than 20 years) - PTFE Tube, Stainless Steel (Fittings, Braid, Helical Wires). Kynar (PVDF Braid), Hastelloy (Fittings, Braid)
Long Life (10 years or more) - Polypropylene (PB Braid, Fittings), Silicone Rubber and EPDM Rubber (Covers)





NOTE; CONDITIONS OF SALE - It is a strict condition that this Order is only accepted and supplied by Aflex Hose on the understanding that the Customer has reviewed, accepted and complied with the Aflex Hose Conditions of Sale as stated on the Aflex Hose website at the time the order was placed.

APPLICABLE TO: CORROFLON, CORROLINE +, BIOFLEX ULTRA, BIOFLON, PHARMALINE N & X, HYPERLINE, VISIFLON AND SMOOTHBORE HOSE TYPES relevant to the PTFE LINER TUBES and SPECIFIED RUBBER COVERS

USP CLASS VI and ISO 10993-5, 6, 10 and 11 GUIDELINES (except Smoothbore, Hyperline & Visiflon)

Natural and Antistatic (AS Grade) PTFE Hose Liners, Platinum Cured Silicone Rubber Covers (White and Clear) and EPDM Rubber Covers (Blue only) have been independently tested in accordance with protocols and are found to conform to the requirements of USP Class VI Chapter <88>.

Natural and Antistatic PTFE Hose liners now also meet the more stringent USP Class VI ISO 10993-6,10 and 11 guidelines at 121°C (250°F) with a "no reaction" classification.

Natural and Antistatic PTFE Hose Liners and Platinum Cured Silicone Rubber Covers (White and Clear) have also been tested in accordance with USP protocols and are found to conform to the requirements of USP Class VI 187>, the L929 MEM Elution Test and are considered non-cytotoxic.

Natural and AS Grade PTFE Hose Liners have now been further tested and have passed the more stringent USP Class VI and ISO 10993-5 guidelines at 121°C (250°F).

• TSE (Transmissible Spongiform Encephalopathy) / BSE (Bovine Spongiform Encephalopathy)
Products manufactured and supplied by Aflex Hose Ltd have not been manufactured from, and have not been in contact with any animal derived materials, during their manufacture, cleaning,

BPSA Leachables and Extractables Testing (except Smoothbore, Hyperline & Visiflon)

Aflex Hose Natural and Antistatic PTFE Hose Liner Tube has been independently tested in accordance with BPSA recommendations, and found to be satisfactory for a particular intended use. Copies of the Test Report are available for specific assessments to be made if required.

Fireproof (Corroline+ and Corroflon Black RC)

Fire Proof in accordance with Specification BS5173 Section 103.13 part 6.2 (Fireproof). Meets the requirements of German Safety Regulation TRBF 131/2.

- Regulation (EC) 1935/2004 on materials and articles intended to come in to contact with food Nat. PTFE (white) and AS PTFE (black)
- Commission Regulation (EU) 10/2011 relating to plastic materials and articles intended to come in to contact with food- Nat. PTFE (white) and AS PTFE (black)
- Regulation (EC) 2023/2006 & 2016/1416 on good manufacturing practice for materials and articles intended to come in to contact with food- Nat. PTFE (white) and AS PTFE (black)

 <u>USP<661> (Bioflex Ultra and Pharmaline N & X only)</u>
 Natural and Antistatic (Carbon filled) hose has been tested in accordance with USP Physiochemical Test for Plastics and meets the criteria of the following reference: USP34, NF 29, 2011. Monograph <661> Containers, Physiochemical Test for Plastics

- None of the following have been used in the manufacture or supply of Aflex Hose products:

 Conflict Materials (tin, tantalum, tungsten, gold) which are sourced from mines of Democratic republic of Congo or its adjoining countries
 - Gluten
 - Bisphenol-A and Melamine
 - Latex/Dry Natural Rubber
 - Phthalates

APPLICABLE TO: BIOFLEX ULTRA, PHARMALINE N & X

3-A Sanitary Standards

Hose assemblies that comply with the 3-A Sanitary standard are marked with the 3-A logo 🔊 and the 3-A standard number 62-02 for hose assemblies. The Aflex 3-A certificate is available from www.3-a.org

APPLICABLE TO: ALL HOSE ASSEMBLIES

Electrical Continuity Requirement

This is to certify that all Aflex Hose Assemblies are Electrically Continuous (EC Grade) between (metallic) End Fittings with an electrical resistance of less than 10² Ohms per hose assembly. Hose assemblies will be marked with "M" in accordance with EN16643,

EXCEPT the following:
All Pharmaline X hose assemblies.
Pharmaline R hose assemblies with "Relink" end fitting

All "TO" Grade (Tube Only) Hose Assemblies
All Visiflon "PB" Grade (Polypropylene Braid) Hose Assemblies

All "AM" Grade (single braid, Aramid Fibre) Hose Assemblies
The Level of less than 10² ohms per hose assembly is well within the requirements of UL 330 (less than 70,000 ohms per assembly) and EN 16643:2016, Type M.

Anti static (AS) Quality
This is to certify that the hose assembly(s) has been tested in accordance with BS EN ISO 8031:2009 and that the electrical resistance between the inner surface of the end fittings meets the Anti static (static dissipative) requirements of EN 16643:2016, which will be between 10³ and 10⁸ Ohms per assembly. Hose assemblies will be marked with an appropriate "Ω" grade for static dissipative construction in accordance with EN 16643:2016.

Electro polished End Fitting Requirements

This is to certify that all Aflex Hose assemblies that include a non-PTFE lined 316L SS Sanitary Triclamp (or Triclover) end fitting, that such end fittings are internally electro polished and passivated to a surface finish of 15µin Ra or less. Also for any fittings for which electro polishing is requested as a special added requirement.

Authorised Signature:

For and on behalf of Aflex Hose Ltd





PRESSURE TEST CERTIFICATE & CERTIFICATES OF CONFORMANCE

For: Aflex PTFE Hose, supplied as Loose Hose or as Hose Assemblies and Loose Fittings

CERTIFICATE NO: AFH/842/202121/002

DESPATCH DATE: 22 Nov 2019 MANUFACTURING DATE: Q4/2019

ORDER DETAILS: Customer: HUBER S.A.

Customer Order No: H.2018/19

Aflex Order No: 187437 / 2 Aflex Despatch Note No: 202121

PRODUCT SUPPLIED (Loose or Assembled)

Product Type and Grade: 1" CORROFLON GP.SS

EC

Quantity and Units: 2 OFF

HOSE ASSEMBLIES ONLY

End (1): 1.00 PN40 SWIVEL FLANGE, PTFE LINED, 1.4404, L/F

End (2): 1.00 PN40 SWIVEL FLANGE, PTFE LINED, 1.4404, L/F

Hose Assembly Length: 1.500

Aflex Hose Serial No (s): 613796 613797

Customer Tag No (s):

PRESSURE TEST CERTIFICATE (Hose Assemblies Only)

This is to certify that the Hose Assemblies supplied were *all pressure tested using re-circulated, UV Filtered, deionised water, in accordance with BS EN 1402:2009 clause 8.1 "Proof Hold Test", and that the Hose Assemblies all passed this test without leakage, cracking, abrupt distortion, or other signs of failure.

Test Pressure (bar): 46.50

(Applied for at least 1 minute)

*Note: Smoothbore hose assemblies supplied in quantities more than 10, only 10% are pressure tested

CERTIFICATE OF CONFORMANCE

CERTIFICATE OF CONFORMANCE

This is to certify that the product(s) supplied have been manufactured and tested in accordance with the requirements of the Customer Order, and conform to these requirements. This is to certify that the product (s) were also manufactured in accordance with Aflex Hose Manufacturing, Inspection and Test Procedures, in accordance with Aflex Hose BS-EN ISO 9001:2015 and IATF 16949:2015 Quality Management Systems, audited and certified by BSI.

CERTIFICATE OF CONFORMANCE to INTERNATIONAL STANDARDS

This is to certify that the Hose (s) supplied, as identified above, conform to the relevant requirements of the International Standards as specified below:

APPLICABLE TO: ALL HOSE TYPES, relevant to: THE PTFE LINER TUBES

FDA 21 CFR 177.1550

The PTFE material used to manufacture all the PTFE liner tubes, both natural and AS (Antistatic) grades, conforms to the FDA requirements of 21 CFR 177.1550

• FDA 21 CFR 178.3297 and EN 16643 (AS Grades only)
The Antistatic (AS Grade) PTFE Liner tubes for all hose products conform to the requirements of 21 CFR 178.3297 and EN 16643, requiring that the carbon black additive is high purity furnace black, less than 2.5% by weight.

AS Grade Liner tubes also conform to the requirements of EN 16643, requiring an electrical resistance between the hose liner and an end fitting of between 10³ and 10⁸ ohms.

3-A Sanitary Standards
 The PTFE material used to manufacture the PTFE liner tubes conforms to the requirements of the 3-A Sanitary Standards.

SAE J 1737 (Automotive Fuel Hose)

Natural and Antistatic PTFE lined hose products have been tested, and conformed to the automotive fuel diffusion requirement of SAE J1737.

 Reach/RoHS

We declare that to the best of our knowledge the articles we provide in the form of PTFE Flexible Hose and Hose Assemblies are compliant to restrictions listed in the SVHC Candidate list. ASME BPE

We confirm that the PTFE hose liners are manufactured from PTFE polymer which complies with the Material of Construction requirements of ASME BPE.

MATERIAL CERTIFICATION TO EN10204-3.1

Separately available upon request for the Components supplied Warranty Period

Aflex Hose Ltd warrants its products to be free from faulty materials or manufacturing defects from the date of the initial sale, for 24 months

STORAGE PERIODS FOR AFLEX PRODUCTS

• STORAGE PERIODS FOR AFLEX PRODUCTS
The storage periods quoted assume that all components are stored in a manner to optimise the storage periods as stated in BS ISO 2230:2002 clause 6, 6.1 to 6.2.13
Storage Life by Material;
Indefinite Life (more than 20 years) - PTFE Tube, Stainless Steel (Fittings, Braid, Helical Wires). Kynar (PVDF Braid), Hastelloy (Fittings, Braid)
Long Life (10 years or more) - Polypropylene (PB Braid, Fittings), Silicone Rubber and EPDM Rubber (Covers)





NOTE: CONDITIONS OF SALE - It is a strict condition that this Order is only accepted and supplied by Aflex Hose on the understanding that the Customer has reviewed, accepted and complied with the Aflex Hose Conditions of Sale as stated on the Aflex Hose website at the time the order was placed.

APPLICABLE TO: CORROFLON, CORROLINE +, BIOFLEX ULTRA, BIOFLON, PHARMALINE N & X, HYPERLINE, VISIFLON AND SMOOTHBORE HOSE TYPES relevant to the PTFE LINER TUBES and SPECIFIED RUBBER COVERS

• USP CLASS VI and ISO 10993-5, 6, 10 and 11 GUIDELINES (except Smoothbore, Hyperline & Visiflon)

Natural and Antistatic (AS Grade) PTFE Hose Liners, Platinum Cured Silicone Rubber Covers (White and Clear) and EPDM Rubber Covers (Blue only) have been independently tested in accordance with protocols and are found to conform to the requirements of USP Class VI Chapter <88>.

Natural and Antistatic PTFE Hose Liners and Platinum Cured Silicone Rubber Covers (White and Clear) have also been tested in accordance with USP protocols and are found to conform to

the requirements of USP Class VI <87>, the L929 MEM Elution Test and are considered non-cytotoxic.

Natural and AS Grade PTFE Hose Liners have now been further tested and have passed the more stringent USP Class VI and ISO 10993-5 guidelines at 121°C (250°F).

• <u>TSE (Transmissible Spongiform Encephalopathy) / BSE (Bovine Spongiform Encephalopathy)</u>
Products manufactured and supplied by Aflex Hose Ltd have not been manufactured from, and have not been in contact with any animal derived materials, during their manufacture, cleaning. finishing or packaging.

• <u>BPSA Leachables and Extractables Testing (except Smoothbore, Hyperline & Visiflon)</u>
Aflex Hose Natural and Antistatic PTFE Hose Liner Tube has been independently tested in accordance with BPSA recommendations, and found to be satisfactory for a particular intended use.
Copies of the Test Report are available for specific assessments to be made if required.

• Fireproof (Corroline+ and Corroflon Black RC)
Fire Proof in accordance with Specification BS5173 Section 103.13 part 6.2 (Fireproof). Meets the requirements of German Safety Regulation TRBF 131/2.

- Regulation (EC) 1935/2004 on materials and articles intended to come in to contact with food Nat. PTFE (white) and AS PTFE (black)
- Commission Regulation (EU) 10/2011 relating to plastic materials and articles intended to come in to contact with food- Nat. PTFE (white) and AS PTFE (black)
- Regulation (EC) 2023/2006 & 2016/1416 on good manufacturing practice for materials and articles intended to come in to contact with food- Nat. PTFE (white) and AS PTFE (black)

• <u>USP<661> (Bioflex Ultra and Pharmaline N & X only)</u>
Natural and Antistatic (Carbon filled) hose has been tested in accordance with USP Physiochemical Test for Plastics and meets the criteria of the following reference: USP34, NF 29, 2011. Monograph <661> Containers, Physiochemical Test for Plastics

- None of the following have been used in the manufacture or supply of Aflex Hose products:

 Conflict Materials (tin, tantalum, tungsten, gold) which are sourced from mines of Democratic republic of Congo or its adjoining countries

 - Bisphenol-A and Melamine
 - Latex/Dry Natural Rubber
 - Phthalates

APPLICABLE TO: BIOFLEX ULTRA, PHARMALINE N & X

Hose assemblies that comply with the 3-A Sanitary standard are marked with the 3-A logo 🔊 and the 3-A standard number 62-02 for hose assemblies. The Aflex 3-A certificate is available

APPLICABLE TO: ALL HOSE ASSEMBLIES

Electrical Continuity Requirement

This is to certify that all Aflex Hose Assemblies are Electrically Continuous (EC Grade) between (metallic) End Fittings with an electrical resistance of less than 10² Ohms per hose assembly. Hose assemblies will be marked with "M" in accordance with EN16643,

EXCEPT the following:

All Pharmaline X hose assemblies

Pharmaline R hose assemblies with "Relink" end fitting All "TO" Grade (Tube Only) Hose Assemblies

All Visifion "PB" Grade (Polypropylene Braid) Hose Assemblies
All "AM" Grade (single braid, Aramid Fibre) Hose Assemblies
The Level of less than 10² ohms per hose assembly is well within the requirements of UL 330 (less than 70,000 ohms per assembly) and EN 16643:2016, Type M.

Anti static (AS) Quality
This is to certify that the hose assembly(s) has been tested in accordance with BS EN ISO 8031:2009 and that the electrical resistance between the inner surface of the end fittings meets the Anti static (static dissipative) requirements of EN 16643:2016, which will be between 10³ and 10⁸ Ohms per assembly. Hose assemblies will be marked with an appropriate "Ω" grade for static dissipative construction in accordance with EN 16643:2016.

Electro polished End Fitting Requirements

This is to certify that all Aflex Hose assemblies that include a non-PTFE lined 316L SS Sanitary Triclamp (or Triclover) end fitting, that such end fittings are internally electro polished and passivated to a surface finish of 15µin Ra or less. Also for any fittings for which electro polishing is requested as a special added requirement.

Authorised Signature:

For and on behalf of Aflex Hose Ltd





PRESSURE TEST CERTIFICATE & CERTIFICATES OF CONFORMANCE

For: Aflex PTFE Hose, supplied as Loose Hose or as Hose Assemblies and Loose Fittings

CERTIFICATE NO: AFH/842/202121/003

DESPATCH DATE: 22 Nov 2019 **MANUFACTURING DATE: Q4/2019**

ORDER DETAILS: Customer: HUBER S.A. Customer Order No: H.2018/19

Aflex Order No: 187437 / 3 Aflex Despatch Note No: 202121

PRODUCT SUPPLIED (Loose or Assembled)

Product Type and Grade: 1" CORROFLON GP,SS

Quantity and Units: 2 OFF

HOSE ASSEMBLIES ONLY

End (1): 1.00 PN40 SWIVEL FLANGE, PTFE LINED, 1.4404, L/F

End (2): 1.00 PN40 SWIVEL FLANGE, PTFE LINED, 1.4404, L/F

Hose Assembly Length: 2.000

Aflex Hose Serial No (s): 613798 613799

Customer Tag No (s):

PRESSURE TEST CERTIFICATE (Hose Assemblies Only)

This is to certify that the Hose Assemblies supplied were *all pressure tested using re-circulated, UV Filtered, deionised water, in accordance with BS EN 1402:2009 clause 8.1 "Proof Hold Test", and that the Hose Assemblies all passed this test without leakage, cracking, abrupt distortion, or other signs of failure.

Test Pressure (bar): 46.50

(Applied for at least 1 minute)

*Note: Smoothbore hose assemblies supplied in quantities more than 10, only 10% are pressure tested

CERTIFICATE OF CONFORMANCE

This is to certify that the product(s) supplied have been manufactured and tested in accordance with the requirements of the Customer Order, and conform to these requirements. This is to certify that the product (s) were also manufactured in accordance with Aflex Hose Manufacturing, Inspection and Test Procedures, in accordance with Aflex Hose BS-EN ISO 9001:2015 and IATF 16949:2015 Quality Management Systems, audited and certified by BSI.

CERTIFICATE OF CONFORMANCE to INTERNATIONAL STANDARDS

This is to certify that the Hose (s) supplied, as identified above, conform to the relevant requirements of the International Standards as specified below:

APPLICABLE TO: ALL HOSE TYPES, relevant to: THE PTFE LINER TUBES

FDA 21 CFR 177.1550

The PTFE Inner tubes, both natural and AS (Antistatic) grades, conforms to the FDA requirements of 21 CFR 177.1550

FDA 21 CFR 178.3297 and EN 16643 (AS Grades only)

The Antistatic (AS Grade) PTFE Liner tubes for all hose products conform to the requirements of 21 CFR 178.3297 and EN 16643, requiring that the carbon black additive is high purity furnace black, less than 2.5% by weight.

AS Grade Liner tubes also conform to the requirements of EN 16643, requiring an electrical resistance between the hose liner and an end fitting of between 103 and 108 ohms.

<u>3-A Sanitary Standards</u>

The PTFE material used to manufacture the PTFE liner tubes conforms to the requirements of the 3-A Sanitary Standards.

SAE J 1737 (Automotive Fuel Hose)
Natural and Antistatic PTFE lined hose products have been tested, and conformed to the automotive fuel diffusion requirement of SAE J1737.

We declare that to the best of our knowledge the articles we provide in the form of PTFE Flexible Hose and Hose Assemblies are compliant to restrictions listed in the SVHC Candidate list. ASME BPE

We confirm that the PTFE hose liners are manufactured from PTFE polymer which complies with the Material of Construction requirements of ASME BPE.

We confirm that the PTFE hose liners are manufactured from PTFE polymer which complies with the Material of Construction requirements of ASME BPE.

MATERIAL CERTIFICATION TO EN10204-3.1
Separately available upon request for the Components supplied

<u>Warranty Period</u>

Aflex Hose Ltd warrants its products to be free from faulty materials or manufacturing defects from the date of the initial sale, for 24 months

STORAGE PERIODS FOR AFLEX PRODUCTS

• STORAGE PERIODS FOR AFLEA PRODUCTS
The storage periods quoted assume that all components are stored in a manner to optimise the storage periods as stated in BS ISO 2230:2002 clause 6, 6.1 to 6.2.13
Storage Life by Material;
Indefinite Life (more than 20 years) - PTFE Tube, Stainless Steel (Fittings, Braid, Helical Wires). Kynar (PVDF Braid), Hastelloy (Fittings, Braid)
Long Life (10 years or more) - Polypropylene (PB Braid, Fittings), Silicone Rubber and EPDM Rubber (Covers)





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APPLICABLE TO: CORROFLON, CORROLINE +, BIOFLEX ULTRA, BIOFLON, PHARMALINE N & X, HYPERLINE, VISIFLON AND SMOOTHBORE HOSE TYPES relevant to the PTFE LINER TUBES and SPECIFIED RUBBER COVERS

USP CLASS VI and ISO 10993-5, 6, 10 and 11 GUIDELINES (except Smoothbore, Hyperline & Visiflon)

Natural and Antistatic (AS Grade) PTFE Hose Liners, Platinum Cured Silicone Rubber Covers (White and Clear) and EPDM Rubber Covers (Blue only) have been independently tested in accordance with protocols and are found to conform to the requirements of USP Class VI Chapter <88>.

Natural and Antistatic PTFE Hose liners now also meet the more stringent USP Class VI ISO 10993-6,10 and 11 guidelines at 121°C (250°F) with a "no reaction" classification

Natural and Antistate FTFE Hose Liners and Platinum Cured Silicone Rubber Covers (White and Clear) have also been tested in accordance with USP protocols and are found to conform to the requirements of USP Class VI <87>, the L929 MEM Elution Test and are considered non-cytotoxic. Natural and AS Grade PTFE Hose Liners have now been further tested and have passed the more stringent USP Class VI and ISO 10993-5 guidelines at 121°C (250°F).

• <u>TSE (Transmissible Spongiform Encephalopathy) / BSE (Bovine Spongiform Encephalopathy)</u>
Products manufactured and supplied by Aflex Hose Ltd have not been manufactured from, and have not been in contact with any animal derived materials, during their manufacture, cleaning. finishing or packaging.

• BPSA Leachables and Extractables Testing (except Smoothbore, Hyperline & Visiflon)

Aflex Hose Natural and Antistatic PTFE Hose Liner Tube has been independently tested in accordance with BPSA recommendations, and found to be satisfactory for a particular intended use. Copies of the Test Report are available for specific assessments to be made if required.

• <u>Fireproof (Corroline+ and Corroflon Black RC)</u>
Fire Proof in accordance with Specification BS5173 Section 103.13 part 6.2 (Fireproof). Meets the requirements of German Safety Regulation TRBF 131/2.

- Regulation (EC) 1935/2004 on materials and articles intended to come in to contact with food Nat. PTFE (white) and AS PTFE (black)
- Commission Regulation (EU) 10/2011 relating to plastic materials and articles intended to come in to contact with food- Nat. PTFE (white) and AS PTFE (black)
- Regulation (EC) 2023/2006 & 2016/1416 on good manufacturing practice for materials and articles intended to come in to contact with food- Nat. PTFE (white) and AS PTFE (black)

• <u>USP<661> (Bioflex Ultra and Pharmaline N & X only)</u>
Natural and Antistatic (Carbon filled) hose has been tested in accordance with USP Physiochemical Test for Plastics and meets the criteria of the following reference: USP34, NF 29, 2011.
Monograph <661> Containers, Physiochemical Test for Plastics

None of the following have been used in the manufacture or supply of Aflex Hose products:

- Conflict Materials (tin, tantalum, tungsten, gold) which are sourced from mines of Democratic republic of Congo or its adjoining countries
- Gluten
- Bisphenol-A and Melamine
- Latex/Dry Natural Rubber
- Phthalates

APPLICABLE TO: BIOFLEX ULTRA, PHARMALINE N & X

3-A Sanitary Standards

Hose assemblies that comply with the 3-A Sanitary standard are marked with the 3-A logo 🔊 and the 3-A standard number 62-02 for hose assemblies. The Aflex 3-A certificate is available from www.3-a.org

APPLICABLE TO: ALL HOSE ASSEMBLIES

Electrical Continuity Requirement
This is to certify that all Aflex Hose Assemblies are Electrically Continuous (EC Grade) between (metallic) End Fittings with an electrical resistance of less than 10² Ohms per hose assembly. Hose assemblies will be marked with "M" in accordance with EN16643,

EXCEPT the following:

All Pharmaline X hose assemblies.
Pharmaline R hose assemblies with "Relink" end fitting

All "TO" Grade (Tube Only) Hose Assemblies All Visiflon "PB" Grade (Polypropylene Braid) Hose Assemblies

All "AM" Grade (single braid, Aramid Fibre) Hose Assemblies
The Level of less than 10² ohms per hose assembly is well within the requirements of UL 330 (less than 70,000 ohms per assembly) and EN 16643:2016, Type M.

Anti static (AS) Quality

This is to certify that the hose assembly(s) has been tested in accordance with BS EN ISO 8031:2009 and that the electrical resistance between the inner surface of the end fittings meets the Anti static (static dissipative) requirements of EN 16643:2016, which will be between 10³ and 10⁸ Ohms per assembly. Hose assemblies will be marked with an appropriate "Ω" grade for static dissipative construction in accordance with EN 16643:2016.

Electro polished End Fitting Requirements

This is to certify that all Aflex Hose assemblies that include a non-PTFE lined 316L SS Sanitary Triclamp (or Triclover) end fitting, that such end fittings are internally electro polished and passivated to a surface finish of 15µin Ra or less. Also for any fittings for which electro polishing is requested as a special added requirement.

Authorised Signature:

For and on behalf of Aflex Hose Ltd





PRESSURE TEST CERTIFICATE & CERTIFICATES OF CONFORMANCE

For: Aflex PTFE Hose, supplied as Loose Hose or as Hose Assemblies and Loose Fittings

CERTIFICATE NO: AFH/842/202121/004

22 Nov 2019 **DESPATCH DATE: MANUFACTURING DATE: Q4/2019**

ORDER DETAILS:

Customer: HUBER S.A. Customer Order No: H.2018/19 Aflex Order No: 187437 / 4 Aflex Despatch Note No: 202121

PRODUCT SUPPLIED (Loose or Assembled)

Product Type and Grade: 1" CORROFLON GP.SS Quantity and Units: 2 OFF

HOSE ASSEMBLIES ONLY

End (1): 1.00 PN40 SWIVEL FLANGE, PTFE LINED, 1.4404, L/F

End (2): 1.00 PN40 SWIVEL FLANGE, PTFE LINED, 1.4404, L/F

Hose Assembly Length: 3.000

Aflex Hose Serial No (s): 613800 613801

Customer Tag No (s):

PRESSURE TEST CERTIFICATE (Hose Assemblies Only)

This is to certify that the Hose Assemblies supplied were *all pressure tested using re-circulated, UV Filtered, deionised water, in accordance with BS EN 1402:2009 clause 8.1 "Proof Hold Test", and that the Hose Assemblies all passed this test without leakage, cracking, abrupt distortion, or other signs of failure.

Test Pressure (bar): 46.50 (Applied for at least 1 minute)

*Note: Smoothbore hose assemblies supplied in quantities more than 10, only 10% are pressure tested

CERTIFICATE OF CONFORMANCE

CERTIFICATE OF CONFORMANCE

This is to certify that the product(s) supplied have been manufactured and tested in accordance with the requirements of the Customer Order, and conform to these requirements. This is to certify that the product (s) were also manufactured in accordance with Aflex Hose Manufacturing, Inspection and Test Procedures, in accordance with Aflex Hose BS-EN ISO 9001:2015 and IATF 16949:2015 Quality Management Systems, audited and certified by BSI.

CERTIFICATE OF CONFORMANCE to INTERNATIONAL STANDARDS

This is to certify that the Hose (s) supplied, as identified above, conform to the relevant requirements of the International Standards as specified below:

APPLICABLE TO: ALL HOSE TYPES, relevant to: THE PTFE LINER TUBES

• FDA 21 CFR 177.1550
The PTFE material used to manufacture all the PTFE liner tubes, both natural and AS (Antistatic) grades, conforms to the FDA requirements of 21 CFR 177.1550

• FDA 21 CFR 178.3297 and EN 16643 (AS Grades only)
The Antistatic (AS Grade) PTFE Liner tubes for all hose products conform to the requirements of 21 CFR 178.3297 and EN 16643, requiring that the carbon black additive is high purity furnace black, less than 2.5% by weight. AS Grade Liner tubes also conform to the requirements of EN 16643, requiring an electrical resistance between the hose liner and an end fitting of between 10³ and 10⁸ ohms.

3-A Sanitary Standards
 The PTFE material used to manufacture the PTFE liner tubes conforms to the requirements of the 3-A Sanitary Standards.

SAE J 1737 (Automotive Fuel Hose)

Natural and Antistatic PTFE lined hose products have been tested, and conformed to the automotive fuel diffusion requirement of SAE J1737.

Reach/RoHS

We declare that to the best of our knowledge the articles we provide in the form of PTFE Flexible Hose and Hose Assemblies are compliant to restrictions listed in the SVHC Candidate list. ASME BPE
We confirm that the PTFE hose liners are manufactured from PTFE polymer which complies with the Material of Construction requirements of ASME BPE.

MATERIAL CERTIFICATION TO EN10204-3.1

Separately available upon request for the Components supplied

Warranty Period

Aflex Hose Ltd warrants its products to be free from faulty materials or manufacturing defects from the date of the initial sale, for 24 months

STORAGE PERIODS FOR AFLEX PRODUCTS

The storage periods quoted assume that all components are stored in a manner to optimise the storage periods as stated in BS ISO 2230:2002 clause 6, 6.1 to 6.2.13 Storage Life by Material;

Indefinite Life (more than 20 years) - PTFE Tube, Stainless Steel (Fittings, Braid, Helical Wires). Kynar (PVDF Braid), Hastelloy (Fittings, Braid) Long Life (10 years or more) - Polypropylene (PB Braid, Fittings), Silicone Rubber and EPDM Rubber (Covers)





NOTE; CONDITIONS OF SALE - It is a strict condition that this Order is only accepted and supplied by Aflex Hose on the understanding that the Customer has reviewed, accepted and complied with the Aflex Hose Conditions of Sale as stated on the Aflex Hose website at the time the order was placed

APPLICABLE TO: CORROFLON, CORROLINE +, BIOFLEX ULTRA, BIOFLON, PHARMALINE N & X, HYPERLINE, VISIFLON AND SMOOTHBORE HOSE TYPES relevant to the PTFE LINER TUBES and SPECIFIED RUBBER COVERS

• <u>USP CLASS VI and ISO 10993-5, 6, 10 and 11 GUIDELINES (except Smoothbore, Hyperline & Visiflon)</u>
Natural and Antistatic (AS Grade) PTFE Hose Liners, Platinum Cured Silicone Rubber Covers (White and Clear) and EPDM Rubber Covers (Blue only) have been independently tested in accordance with protocols and are found to conform to the requirements of USP Class VI Chapter <88>.

Natural and Antistatic PTFE Hose liners now also meet the more stringent USP Class VI ISO 10993-6,10 and 11 guidelines at 121°C (250°F) with a "no reaction" classification.

Natural and Antistatic PTFE Hose Liners and Platinum Cured Silicone Rubber Covers (White and Clear) have also been tested in accordance with USP protocols and are found to conform to

the requirements of USP Class VI <87>, the L929 MEM Elution Test and are considered non-cytotoxic. Natural and AS Grade PTFE Hose Liners have now been further tested and have passed the more stringent USP Class VI and ISO 10993-5 guidelines at 121°C (250°F).

• <u>TSE (Transmissible Spongiform Encephalopathy) / BSE (Bovine Spongiform Encephalopathy)</u>
Products manufactured and supplied by Aflex Hose Ltd have not been manufactured from, and have not been in contact with any animal derived materials, during their manufacture, cleaning, finishing or packaging.

• <u>BPSA Leachables and Extractables Testing (except Smoothbore, Hyperline & Visiflon)</u>
Aflex Hose Natural and Antistatic PTFE Hose Liner Tube has been independently tested in accordance with BPSA recommendations, and found to be satisfactory for a particular intended use.
Copies of the Test Report are available for specific assessments to be made if required.

• <u>Fireproof (Corroline+ and Corroflon Black RC)</u>
Fire Proof in accordance with Specification BS5173 Section 103.13 part 6.2 (Fireproof). Meets the requirements of German Safety Regulation TRBF 131/2.

- Regulation (EC) 1935/2004 on materials and articles intended to come in to contact with food Nat. PTFE (white) and AS PTFE (black)
- Commission Regulation (EU) 10/2011 relating to plastic materials and articles intended to come in to contact with food- Nat. PTFE (white) and AS PTFE (black)
- Regulation (EC) 2023/2006 & 2016/1416 on good manufacturing practice for materials and articles intended to come in to contact with food- Nat. PTFE (white) and AS PTFE (black)

 <u>USP<661> (Bioflex Ultra and Pharmaline N & X only)</u>

Natural and Antistatic (Carbon filled) hose has been tested in accordance with USP Physiochemical Test for Plastics and meets the criteria of the following reference: USP34, NF 29, 2011. Monograph <661> Containers, Physiochemical Test for Plastics

- None of the following have been used in the manufacture or supply of Aflex Hose products:

 Conflict Materials (tin, tantalum, tungsten, gold) which are sourced from mines of Democratic republic of Congo or its adjoining countries
 - Gluten
 - Bisphenol-A and Melamine
 - Latex/Dry Natural Rubber
 - Phthalates

APPLICABLE TO: BIOFLEX ULTRA, PHARMALINE N & X

3-A Sanitary Standards

Hose assemblies that comply with the 3-A Sanitary standard are marked with the 3-A logo 🔊 and the 3-A standard number 62-02 for hose assemblies. The Aflex 3-A certificate is available from www.3-a.org

APPLICABLE TO: ALL HOSE ASSEMBLIES

Electrical Continuity Requirement

This is to certify that all Aflex Hose Assemblies are Electrically Continuous (EC Grade) between (metallic) End Fittings with an electrical resistance of less than 10² Ohms per hose assembly. Hose assemblies will be marked with "M" in accordance with EN16643,

EXCEPT the following: All Pharmaline X hose assemblies

Pharmaline R hose assemblies with "Relink" end fitting All "TO" Grade (Tube Only) Hose Assemblies

All Visition "PB" Grade (Polypropylene Braid) Hose Assemblies
All "AM" Grade (single braid, Aramid Fibre) Hose Assemblies
The Level of less than 10² ohms per hose assembly is well within the requirements of UL 330 (less than 70,000 ohms per assembly) and EN 16643:2016, Type M.

Anti static (AS) Quality

This is to certify that the hose assembly(s) has been tested in accordance with BS EN ISO 8031:2009 and that the electrical resistance between the inner surface of the end fittings meets the Anti static (static dissipative) requirements of EN 16643:2016, which will be between 10⁸ and 10⁸ Ohms per assembly. Hose assemblies will be marked with an appropriate "Ω" grade for static dissipative construction in accordance with EN 16643:2016.

Electro polished End Fitting Requirements
This is to certify that all Aflex Hose assemblies that include a non-PTFE lined 316L SS Sanitary Triclamp (or Triclover) end fitting, that such end fittings are internally electro polished and passivated to a surface finish of 15µin Ra or less. Also for any fittings for which electro polishing is requested as a special added requirement.

Authorised Signature:

For and on behalf of Aflex Hose Ltd

