

# CERTIFICATE F.D.A. APPROVED MATERIALS



**Xtraflex NV**

Paaistraat 13  
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Tel : +(32)-(0)3-680.11.90

Fax : +(32)-(0)3-680.11.99

sales@xtraflex.com  
www.xtraflex.com

VAT nr : ON-BE 0464.871.411

Our reference

Customer Name

Your reference

## Acc to EN 10204:2005 2.2

Date :

Hose	Material type	Lot number

We hereby certify that the hoses supplied against the above order have been manufactured from PTFE which complies with FDA regulation 21 CFR 177.1550 and also meets the requirement of USP Class VI.

All antistatic PTFE hoses contains <2.5% high purity Carbon Black which conforms to FDA requirement 21 CFR 178.3297

For and on behalf of Xtraflex NV,

  
Tom Rombouts  
Quality Manager

The Quality Management System of Xtraflex NV, has been certified according to **NBN-EN-ISO 9001:2008**. the scope covers the manufacturing, assembly, commercialisation and distribution of flexible P.T.F.E. pressure hose & wire braid.



# PRESSURE TEST CERTIFICATE



**Xtraflex NV**

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## Acc to EN 10204:2005 2.2

Date :  
Type hose :  
Length hose :  
Quantity :

Connection 1 type :  
Connection 2 type :

Tested by :  
Inspection :

We hereby certify that the materials described above have been 100% tested and withstood the specified pressure without leaking.

For and on behalf of Xtraflex NV,

  
Tom Rombouts  
Quality Manager

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# CERTIFICATE OF MATERIAL



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**Acc to EN 10204:2005 3.1.**

Date :

Description :

Part type	Material type	Certificate of material

We hereby certify that the materials described above are in accordance with your order and in accordance to our specifications hereby enclosed.

For and on behalf of Xtraflex NV,

  
Tom Rombouts  
Quality Manager

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# CERTIFICATE OF CONFORMITY



**Xtraflex NV**

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## Acc to EN 10204:2005 2.2.

Date :  
Type Hose :  
Length Hose :  
Quantity :

Connection 1 Type :  
Connection 2 Type :

We hereby certify that the materials used in this assembly are in accordance with your order and according to our specifications hereby enclosed.

For and on behalf of Xtraflex NV,

  
Tom Rombouts  
Quality Manager

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# DECLARATION OF COMPLIANCE EC 1935/2004



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## Regulatory Compliance Statement for Food Contact Materials

Date :

We hereby declare that all our bulk hoses and hose assemblies are made from following PTFE grades

- Dupont Teflon® 62-N and 62XT
- Dyneon TFM™ 2070Z
- Daikin F303

All of these suppliers declare that the PTFE has the following status relative to food contact regulations in Europe and the USA:

### **European Union**

Compliant with European Regulation EC1935/2004 and its amendments  
( specifically European Regulation EU10/2011).

### **USA**

Compliant with the FDA regulation 21 CFR 177.1550 § (a) (2) and (b) when used to manufacture moulded/extruded articles.

Xtraflex also had migration tests carried out by an independent laboratory on representative pieces of the above tubing to make sure that all of our PTFE hose products have been processed following the Good Manufacturing Practises Regulation EC 2023/2006EC. These tests were all positive so all is compliant to article 3 of Regulation EC 1935/2004.

This migration test certificate ( IBE-BVI - CFP-11.144 ) can be received upon request.

For and on behalf of Xtraflex NV,

  
Tom Rombouts  
Quality Manager

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# CERTIFICATE OF ANTI-STATIC QUALITY



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## Acc to EN 10204:2005 2.1.

Date :

We hereby certify that the hoses supplied against the above order have been tested in accordance with EN ISO 8031:2009 Clause 7 and meet the requirements of Appendix A having a resistance of between  $10^3 \Omega$  and  $10^8 \Omega$  between the inside of the hose and end fitting.

For and on behalf of Xtraflex NV,

  
Tom Rombouts  
Quality Manager

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# CERTIFICATE OF ATEX CONFORMITY



**Xtraflex NV**

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**Acc to EN ISO 8031:2009 dd. 12/2009 and CLC/TR 50404 dd. 06/2003**

Date :

We hereby certify that the materials used in this assembly are in accordance with EN ISO 8031:2009 dd. 12/2009 and CLC/TR 50404 dd. 06/2003.

Electrostatic properties of these hoses allow use in explosive environments in following industries:

Surface industries:

Dusty environments in areas type 20, 21 and 22 (according to guideline 1999/92/CE).

Gas environments group IIA, IIB & IIC in areas types 0, 1 & 2 (according to guideline (1999/92/CE).

Mining industries:

All extraction types & depths.

For and on behalf of Xtraflex NV,

  
Tom Rombouts  
Quality Manager

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# VACUUM TEST CERTIFICATE



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## Acc to EN 10204:2005 2.2.

Date :  
Type hose :  
Length hose :  
Quantity :

Connection 1 type :  
Connection 2 type :

Vacuum tested : 95 %

We hereby certify that the materials described above have been vacuum tested and withstood the specified vacuum.

For and on behalf of Xtraflex NV,

  
Tom Rombouts  
Quality Manager

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**according to NBN-EN-ISO 9001:2008** the scope covers the manufacturing,  
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# DECLARATION OF CONFORMITY ACCORDING TO DIRECTIVE 97/23/EC



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## Declaration of conformity according to directive 97/23/EC

Date :

Description :  
Type-, Serial-, Identification-No :  
Max. allowable pressure PS :  
Allowable max./min. Temperature TS :  
Diameter DN :  
Year of manufacturing :  
Test pressure PT :  
Testfluid :  
Corresponds to the **Pressure Equipment Directive 97/23/EC**.

Applied conformity assessment procedures:

### **Certificates which are included:**

-Certificate of conformity No. :  
-Certificate of material No. :  
-Testcertificate No. :

For and on behalf of Xtraflex NV,

  
Tom Rombouts  
Quality Manager

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**Degreasing**

**Acc to EN 10204:2005 2.2.**

Date :  
Type hose :  
Length hose :  
Quantity :

Connection 1 type :  
Connection 2 type :

We certify that the assembled hoses have been degreased, dried and were equipped with dust caps. They have been packed in separate plastic bags.

We hereby certify that the materials used in this assembly are in accordance with your order and according to our specifications hereby enclosed.

For and on behalf of Xtraflex NV,

  
Tom Rombouts  
Quality Manager

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**according to NBN-EN-ISO 9001:2008**. the scope covers the manufacturing,  
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**Surface Finish**

**Acc to EN 10204:2005 2.2.**

Date :  
Type hose :  
Length hose :  
Quantity :

Connection 1 type :  
Connection 2 type :

We hereby certify that the materials used in this assembly are in accordance with your order and have been electropolished  $\leq 0,8 \mu\text{m}$ .

For and on behalf of Xtraflex NV,

  
Tom Rombouts  
Quality Manager

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# DECLARATION OF ASBESTOS FREE



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## Declaration and confirmation of asbestos free-products

Date :

This document serves as a declaration and confirmation from the manufacturer, Xtraflex, that asbestos materials are not utilized in any assembly or sub-assembly component during the construction of any of our flexible hoses.

For and on behalf of Xtraflex NV,

  
Tom Rombouts  
Quality Manager

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# DECLARATION OF BPSA



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## BPSA Leachables and Extractables

Date :

We hereby declare that:

Representative samples of Speed-Flow®, Smooth-Flow®, Core-Flow®, and Convo-Flow® natural and antistatic PTFE tube liners have been tested in accordance with BPSA and FDA recommendations.

Trace quantities of chemicals extracted have so far been considered 'not significant' by pharma customers who have studied the results. No free carbon was extracted during the test<sup>1</sup>

<sup>1</sup>Identification and quantification of extractable substances using DI water (deionized water) and ethanol absolute (absolute ethanol (purity = 99.97 %), under accelerated condition, in accordance with BPSA and FDA

For and on behalf of Xtraflex NV,

  
Tom Rombouts  
Quality Manager

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# DECLARATION BSE - TSE



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## Xtraflex Declaration

Date :

We hereby Declare that our hose types :

Tube-Flow®  
Speed-Flow®  
Smooth-Flow®  
Convo-Flow®  
Core-Flow®  
Easy-Flow®

Are free from BSE (Bovine Spongiform Encephalopathy) and TSE (Transmissible Spongiform Encephalopathy).

The above mentioned products do not contain any animal derivatives ingredient.

For and on behalf of Xtraflex NV,

  
Tom Rombouts  
Quality Manager

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# CERTIFICATE OF CONFORMITY 3-A



**Xtraflex NV**

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Our reference

Customer Name

Your reference

## 3-A Sanitary Standards

Date :

We hereby certify that the following products have been manufactured from PTFE which meets the requirements of the 3-A sanitary standards.

Super-Flow®  
Speed-Flow®  
Smooth-Flow®  
Convo-Flow®  
Core-Flow®  
Easy-Flow®

For and on behalf of Xtraflex NV,

  
Tom Rombouts  
Quality Manager

The Quality Management System of Xtraflex NV, has been certified  
**according to NBN-EN-ISO 9001:2008**. the scope covers the manufacturing,  
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# CERTIFICATE OF ELECTRICAL CONTINUITY



**Xtraflex NV**

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## Acc to EN 10204 3.1.

Date :

Measured Resistance :

Part type	Material type	Certificate of material

We hereby certify that the hoses supplied against the above order have been tested in accordance with EN ISO 8031:2009 Clause 5 and comply to the requirements of Appendix A :

Type M <10<sup>2</sup> Ω

Type Ω between 10<sup>3</sup>Ω and 10<sup>8</sup>Ω

For and on behalf of Xtraflex NV,

Tom Rombouts  
Quality Manager

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# DECLARATION OF COMPLIANCE TO FMVSS 106

**Xtraflex NV**

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HRA nr : RPR Antwerpen

**571.106 Federal Motor Vehicle Safety Standard No. 106; Brake hoses**

This standard establishes performance and labeling requirements for hydraulic, air, and vacuum brake hoses, brake hose assemblies, and brake hose fittings for all motor vehicles. The purpose of this standard is to reduce deaths and injuries occurring as a result of brake system failure from pressure or vacuum loss due to hose or hose assembly rupture.

**Xtraflex hereby declares that all the brake hose and brake hose assemblies comply with FMVSS106.**

**Test Requirements**

All the following tests have been done by accredited test laboratories.

- S5.3.1 Constriction
- S5.3.2 Expansion and Burst Strength
- S5.3.3 Whip Resistance
- S5.3.4 Tensile Strength
- S5.3.5 Water Absorption and Burst Strength
- S5.3.6 Water Absorption and Tensile Strength
- S5.3.7 Water Absorption and Whip Resistance
- S5.3.8 Low Temperature Resistance
- S5.3.9 Brake Fluid Compatibility, Constriction and Burst Strength
- S5.3.10 Ozone Resistance
- S5.3.11 End Fitting Corrosion Resistance

The assemblies passed every requirement that is stated in the norm FMVSS 106.

For and on behalf of Xtraflex NV,

Tom Rombouts  
Quality Manager