

CERTIFICATE F.D.A. APPROVED MATERIALS



Xtraflex NV
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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
Hose		

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 26 Class VI <88> at 121°C.

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

Signed for and on behalf of Xtraflex NV

Tom Vermoesen
 General Manager

The Quality Management System of Xtraflex NV, has been certified according to **NBN-EN-ISO 9001:2015**. the scope covers the manufacturing, assembly, commercialisation and distribution of flexible P.T.F.E. pressure hose & wire braid.





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Acc to EN 10204:2005 type 3.1

Date :
Type hose :
Length hose :
Quantity :
Connection 1 type :
Connection 2 type :
Description :

Tested by :
Inspection :

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

Signed for and on behalf of Xtraflex NV

Tom Vermoesen
General Manager

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PRESSURE TEST CERTIFICATE



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Acc to EN 10204:2005 3.1.

Date :
 Hose Assembly :
 Description :

Part type	Material type	Certificate of material
Hose		
Braid		
Coupling		
Ferrule		

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

Signed for and on behalf of Xtraflex NV

Tom Vermoesen
 General Manager

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CERTIFICATE OF MATERIAL

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 :

Description :

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

Signed for and on behalf of Xtraflex NV

Tom Vermoesen
General 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 cetificate (IBE-BVI - CFP-16.025) can be received upon request.

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General Manager

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CERTIFICATE OF ANTI-STATIC QUALITY



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Our reference	Customer Name
Article	Your reference

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 10³ Ω and 10⁸ Ω between the inside of the hose and end fitting.

Signed for and on behalf of Xtraflex NV

Tom Vermoesen
General Manager

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CERTIFICATE OF ATEX CONFORMITY



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Our reference

Customer Name

Your reference

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.

Signed for and on behalf of Xtraflex NV

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Declaration of conformity according to directive 2014/68/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 2014/68/EC.**

Applied conformity assessment procedures:

Certificates which are included:

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

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DECLARATION OF ASBESTOS FREE



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Our reference

Customer Name

Your reference

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.

Signed for and on behalf of Xtraflex NV

Tom Vermoesen
General Manager

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DECLARATION OF BPSA

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Our reference

Customer Name

Your reference

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!

¹Identification 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

Signed for and on behalf of Xtraflex NV

Tom Vermoesen
General Manager

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CERLEACH 2014 v2.0



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Our reference

Customer Name

Your reference

Xtraflex Declaration

Date :

We hereby Declare that our hose types :

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

Are free from BSE (Bovine Spongiform Encephalopathy) and TSE (Transmissible Spongiform Encephalopathy).
The above mentioned products do not contain any animal derivatives ingredient (ADI).

PTFE is complying with the following FDA regulations:

21 CFR 177.1550 and meet requirements of a US Pharmacopeia Class VI

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

Signed for and on behalf of Xtraflex NV

Tom Vermoesen
General Manager

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DECLARATION BSE - TSE

CERTIFICATE OF CONFORMITY 3-A



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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®

Signed for and on behalf of Xtraflex NV

Tom Vemoesen
General Manager

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DECLARATION OF COMPLIANCE TO FMVSS 106



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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.

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General Manager

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CERTIFICATE OF ELECTRICAL CONTINUITY



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Our reference

Customer Name

Your reference

Acc to EN 10204 3.1.

Date :

Measured Resistance : Ω

Part type	Material type	Certificate of material
Hose		
Flange		
Stubend		
Ferrule		

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 $10^2 \Omega$

Signed for and on behalf of Xtraflex NV

Tom Vermoesen
 General Manager

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