

# BIOFLEX ULTRA

## Quality Assurance, Certification and Approvals, and Hose Testing

### EN ISO 9001:2008

Aflex products are all manufactured in accordance with BS EN ISO 9001: 2008 Quality Management Systems independently assessed and registered by National Quality Assurance Limited (NQA).

### EN12115

Bioflex Ultra meets the relevant requirements of EN12115, but the correct specification for the electrical and electrostatic requirements is EN ISO 8031 Annex A.

### TS16949

Aflex Hose Ltd manufactures PTFE flexible hose for the automotive industry in accordance with TS16949 and is assessed and certified by National Quality Assurance Limited (NQA).

### USP Class VI and ISO 10993-5, 6, 10 and 11 guidelines

Natural and Antistatic PTFE Hose Liners, Platinum Cured Silicone Rubber Covers (White and Clear) and EPDM Rubber Cover (Blue) have been independently tested in accordance with USP 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 and 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 Antistatic 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).

### USP <661> Physicochemical Test for Plastics

Natural and Antistatic (Carbon filled) Externally Convuluted Smoothbore PTFE hose has been tested in accordance with USP Physicochemical Test for Plastics and found to meet the criteria of the following reference: USP34, NF 29, 2011. Monograph <661> Containers, Physicochemical Test-Plastics.

### FDA

The Materials used to manufacture the natural PTFE Tube liner conforms to FDA 21 CFR 177.1550, and the antistatic PTFE liner conforms to FDA 21 CFR 178.3297.

### 3-A Sanitary Standards

The PTFE used in the liner is manufactured solely from materials which meet the requirements of the 3-A Sanitary Standards.

### BPSA leachables and extractables testing

Aflex Hose Natural and Antistatic PTFE Hose Liner Tube has been independently tested in accordance with BPSA recommendations, and found to be satisfactory.

Copies of the Test Report are available for specific assessments to be made.

### Flame Resistant

To special order only, Aflex Hose are able to supply hose with a special rubber cover which is compliant with the requirements of BS EN 45545, DIN 5510 and NFF 16101 specifications.

### Pharmaceutical Manufacturers Approvals

Most of the major pharmaceutical manufacturing companies in the world have audited and/or approved Aflex Hose as a Hose Supplier.

### CE Marking (Europe only)

Aflex has been assessed by a notified body and found to comply with the Pressure Equipment Directive 97/23/EC (European Community) Conformity Assessment Module D1, approved to CE Mark applicable hose products, accompanied by a Hose Usage Data Sheet, and a Declaration of Conformity.

### Attestations of Conformity to ATEX Directive 94/9/EC (Potentially Explosive Atmospheres)

Available for hose and assemblies for components used in Gas Zones 1 & 2 and Dust Zones 21 & 22, when applicable.

### Material Certification to EN10204

Available for all the hose or hose assembly components.

### Certificates of Conformity to EN ISO/IEC 17050

Are available for all products.

### Fuel Hose Approval to SAE J1737

Bioflex Ultra hose samples have been tested and approved to SAE J1737 for Automotive Fuel Hose applications.

### Hose Testing

Each assembly is pressure tested to 1.5 times maximum working pressure before despatch, and pressure test certificates can be supplied.

### Fire Resistance to BS5173 Section 103.13 Part 6.2 and 6.3

BK Grade Bioflex Ultra hose assemblies are "Fire Resistant". If DRC-300 is added at both ends, the assemblies are upgraded to "Fire Proof".