

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

### **BS 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).

### **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 & 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 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.

### **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.

### **Pharmaceutical Manufacturers Approvals**

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

### **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.

### **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 BS EN ISO/IEC 17050**

Are available for all products.

### **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**

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