

変更通知：FT.260106-1
変更レベル：Emergency
2026 年 5 月 8 日

WM チューブおよびエレメント適合証明書の更新について

大切なお客様へ：

変更内容

ISO 9001:2015 認証取得メーカーであるワトソン・マーロウ・フルード・テクノロジー・ソリューションズ（WMFTS）は、お客様からのフィードバックに基づいた継続的な改善活動の一環として、適合証明書（CoC）を更新することをお知らせいたします。

弊社のチューブおよびエレメントに付属し、弊社ウェブサイト [Certificates of conformance \(COC\)](#) からダウンロードできます。WMFTS は、業界のベストプラクティスに準拠するため、見直しと更新を行いました。更新後の CoC は以前とは異なる形式となりますが、製造の詳細、ロット番号、供給拠点の品質・コンプライアンス責任者の署名など、チューブ製品に関する情報は引き続き記載されています。すべての新規チューブ CoC は、一貫性を保つため、同一のフォーマットを採用しています。

新しい証明書の例は付録 2 に記載されています。

変更タイプ：

☐	化学的性質	☐	物理的性質	☐	製造プロセス
☐	機能性	☐	原材料	☐	仕様
☐	装置	☐	製造拠点	☐	製造規模
☐	構成	☐	コンタクトパッケージ	☐	ラベリング
☒	文章	☐	テスト方法	☐	サプライチェーン
☐	製造中止	☐	その他：パッケージング		

変更の影響：

チューブ製品の適合性、形状、機能に影響はありません。

チューブ製品の性能や仕様にも影響はありません。

ワトソン・マーロウ社による試験または検証を受けていない未加工原料の物理的特性は、以前は CoC（適合証明書）に記載されていましたが、現在は削除されています。

適用範囲：

以下の製品群について、行動規範（CoC）が更新されます。

Pumpsil® and Pumpsil Loadsure and Y elements
Bioprene® and Bioprene Loadsure and Y elements
PureWeld®XL and PureWeld XL Loadsure and Y elements
Platinum cured Silicone single Braided Hose
Silicone Transfer Tube
Gore® STA-PURE series PCS Loadsure and Y elements
Gore® STA- PURE series PFL Loadsure and Y elements
Accusil™

対象製品：

部品番号については付録 1 を参照してください。

本変更の適用時期：

2026 年 5 月 18 日から新しい認証制度への移行が開始されます。移行期間は 2026 年 5 月 25 日までに完了する予定で、この日以降に製造されるすべての製品には新しい CoC テンプレートが適用されます。

お客様へのお願い：

ご質問がございましたら、WMFTS の担当者までご連絡ください。

<Name of WMFTSG sender>

<job title of WMFTS sender>

<email address of sender>

敬具



Beckie Govier

Product Manager Tubing

Rebecca.govier@wmfts.com

付録 1 : 対象項目

PureWeld XL:	PureWeld XL Loadsure Elements
942.0005.016	942.0064.PFT
942.0016.016	942.0096.PFT
942.0016.R16	942.0120.PFT
942.0016.024	942.0170.PFT
942.0024.016	194.1096.AQ5
942.0032.016	194.1190.FS1
942.0032.R16	194.1120.80A
942.0048.016	
942.0048.R16	
942.0048.024	PureWeld XL Kynar Y Elements
942.0048.R24	
942.0064.016	942.E064.K24
942.0064.R16	942.E080.K24
942.0064.024	942.E096.K24
942.0064.R24	942.E120.K40
942.0080.016	
942.0080.R16	
942.0080.024	
942.0096.024	
942.0096.R24	
942.0096.032	
942.0096.R32	
942.0096.048	
942.0120.040	
942.0127.032	
942.0127.048	
942.0159.032	
942.0159.048	
942.0190.048	
942.0254.048	
194.2096.FU9	
194.2080.FH7	
194.2016.DN7	
194.2254.EK7	
194.2254.X51	
194.1080.FH7	
194.1096.FU9	
194.1190.BW2	
194.1190.EK2	
194.2096.FU9	

Bioprene			Bioprene Kynar Y Elements	Bioprene Loadsure Elements
933.0005.010	933.0048.J16	933.0160.040	933.E016.K24	933.0032.PFT
933.0005.016	933.0048.R16	933.0160.I40	933.E032.K24	933.P032.PFT
933.0005.J16	933.0048.024	933.0170.040	933.E048.K24	933.0064.PFT
933.0005.R16	933.0048.J24	933.0190.032	933.E064.K24	933.P064.PFT
933.0008.016	933.0048.R24	933.0190.I32	933.E080.K24	933.0096.PFT
933.0008.J16	933.0064.016	933.0190.048	933.E080.K40	933.P120.PFT
933.0008.R16	933.0064.J16	933.0190.I48	933.E096.K24	933.P127.82E
933.0010.010	933.0064.R16	933.0254.048	933.E120.K40	933.P127.G48
933.0010.C10	933.0064.J24	933.0254.I48	933.E160.K40	933.P159.G48
933.0016.008	933.0064.032	933.0254.K48	933.E12B.64F	933.P170.PFT
933.0016.016	933.0064.024	933.0254.U90	933.E12B.G48	933.P190.G48
933.0016.J16	933.0064.R24	933.B008.B16	933.P096.P24	933.P254.G48
933.0016.R16	933.0064.R32	933.BL32.G16		933.H032.PFT
933.0016.B16	933.0064.I32	933.JE08.B16	193.3E48.HP5	933.0254.PFT
933.0016.024	933.0080.016	933.JE16.B16		933.0190.PFT
933.0016.J24	933.0080.J16	933.JE24.B16		933.0170.PFT
933.0016.R24	933.0080.R16	933.JE32.B16		933.0159.PFT
933.0016.40B	933.0080.024	933.JE48.B16		933.0127.PFT
933.0020.010	933.0080.J24	193.3010.HL3		933.0120.PFT
933.0020.B10	933.0080.R24	193.BL16.DH7		
933.002A.B10	933.0080.T24			
933.0023.K22	933.0080.040			
933.0024.016	933.0080.I40			088.0250.E0P
933.0024.R16	933.0096.024			088.T250.00G
933.0024.J16	933.0096.J24			088.T250.00P
933.0030.010	933.0096.R24			088.T250.E0G
933.0030.A10	933.0096.032			088.T250.E0P
933.0030.B10	933.0096.I32			193.3020.W08
933.003A.B10	933.0096.R32			193.3096.40G
933.0032.016	933.0096.048			193.3120.DZ3
933.0032.R16	933.0096.I48			193.3120.JD4
933.0032.J16	933.0120.040			193.3254.DZ2
933.0032.024	933.0120.I40			193.3P12.FY7
933.0032.R24	933.0127.032			193.3P17.EK9
933.0032.J24	933.0127.I32			
933.0032.A01	933.0127.048			
933.0032.C16	933.0127.I48			
933.0032.D16	933.0127.08A			
933.0040.010	933.0159.032			
933.0040.016	933.0159.I32			
933.0040.B16	933.0159.048			
933.0048.016	933.0159.I48			

Pumpsil				
913.A005.016	913.A048.032	913.B048.R32	913.B100.030	191.3064.67A
913.B005.R16	913.A048.I32	913.B050.025	913.A120.040	191.3190.EN8
913.AJ05.016	913.B048.R32	913.BX50.030	913.A120.I40	191.3190.FU6
913.A005.024	913.B050.025	913.B057.026	913.A127.032	191.3254.EN5
913.AJ05.024	913.BX50.030	913.B060.020	913.A127.I32	191.3254.EN6
913.A008.016	913.B057.026	913.A064.016	913.B127.032	191.3A00.BQ6
913.AJ08.016	913.B060.020	913.AJ64.016	913.B127.R32	191.3A01.BQ7
913.B008.R16	913.A064.016	913.B064.R16	913.B127.A32	191.3A02.FE6
913.A008.024	913.AJ64.016	913.B064.016	913.A127.A05	191.3A02.FE7
913.AJ08.024	913.B064.R16	913.A064.024	913.A127.048	191.3A03.BD1
913.B008.R24	913.BA64.R16	913.AJ64.024	913.A127.I48	191.3A03.BQ8
913.A012.016	913.B064.016	913.B064.R24	913.A159.032	191.3A04.BQ9
913.AJ12.016	913.A064.024	913.B064.A24	913.A159.I32	191.3A19.CN5
913.B012.R16	913.AJ64.024	913.A064.032	913.A159.048	191.3A19.EE5
913.AJ16.016	913.B064.R24	913.A064.I32	913.A159.I48	191.3A24.GQ8
913.A016.016	913.B064.A24	913.B064.R32	913.A160.040	191.3A30.GA9
913.B016.R16	913.A064.032	913.B070.030	913.A160.I40	191.3A32.GA5
913.BL16.B16	913.A064.I32	913.A080.016	913.A170.040	191.3A32.GA6
913.AS16.016	913.B064.R32	913.AJ80.016	913.B190.032	191.3A32.GA7
913.A016.024	913.B070.030	913.B080.R16	913.A190.048	913.M016.R16
913.AJ16.024	913.A080.016	913.B080.020	913.A190.I48	913.M032.R16
913.B016.R24	913.AJ80.016	913.A080.024	913.B190.H48	913.M032.R24
913.A024.016	913.B080.R16	913.AJ80.024	913.B19C.048	913.M048.R16
913.AJ24.016	913.B080.020	913.B080.R24	913.A254.048	913.M048.R24
913.B030.015	913.A080.024	913.B080.024	913.A254.I48	913.M064.R16
913.A032.016	913.AJ80.024	913.B080.H24	913.BX30.40	913.M064.R24
913.AJ32.016	913.B080.R24	913.A080.040	913.BX80.A20	913.M064.R32
913.B032.R16	913.B080.024	913.A080.I40	913.BX50.030	913.M080.R16
913.B032.A16	913.B080.H24	913.A096.024	913.BZ31.R16	913.M080.R24
913.A032.019	913.A080.040	913.AJ96.024	913.BP95.R28	913.M096.024
913.A032.024	913.A080.I40	913.B096.R24	913.BZ31.R16	913.M096.R32
913.AJ32.024	913.A096.024	913.BQ96.024	191.3A30.GA9	913.M127.032
913.B032.R24	913.AJ96.024	913.AJ96.032	191.3A24.GQ8	913.M127.048
913.B040.020	913.B096.R24	913.A096.032	191.3A60.GB1	913.M159.032
913.A048.016	913.BQ96.024	913.A096.I32	191.3B50.GR7	913.M159.048
913.AJ48.016	913.AJ96.032	913.B096.A32	191.3080.FT4	913.M190.048
913.B048.R16	913.A096.032	913.B096.R32	191.3024.66A	913.M254.048
913.BA48.G16	913.AJ48.024	913.B096.032	191.3032.BJ4	
913.A048.024	913.B048.R24	913.A096.048	191.3048.BJ3	
913.AJ48.024	913.A048.032	913.A096.I48	191.3064.DA7	113.A001.N80
913.B048.R24	913.A048.I32	913.B100.025	191.3064.AH9	

Pumpsil Quick Release Elements	Pumpsil Y Element
913.A032.PFQ	913.AE05.K24
913.A064.PFQ	913.AE08.K24
913.A096.PFQ	913.AE16.K24
Pumpsil Loadsure	913.AE32.K24
913.A032.PFT	913.AE48.K24
913.A064.PFT	913.AE64.K24
913.A096.PFT	913.AE80.K24
913.A120.PFT	913.AE80.K40
913.A170.PFT	913.AE96.K40
913.A127.PFT	913.A12E.K40
913.A159.PFT	913.A16E.K40
913.A190.PFT	
913.A254.PFT	191.3E32.HM5
191.3A17.EW8	191.3E48.HM4
Pumpsil Loadsure Cam & Groove	
913.A120.PPC	
913.A170.PPC	
913.A127.PPC	
913.A159.PPC	
913.A190.PPC	
913.A254.PPC	

Accusil	Accusil Kynar Y elements
84-103-005	84-510-016
84-103-008	84-510-032
84-103-012	84-510-048
84-103-016	84-510-064
84-103-032	84-510-080
84-103-048	84-510-096
84-103-060	
84-103-080	
84-103-A01	
84-103-A02	
84-103-A03	
184.0103.GL2	84-510-080
184.0103.GL3	84-510-096
MRZ3045	MNAZ5340A
84-104-005	
84-104-008	190.1632.CX8
84-104-012	190.3224.GW3
84-104-016	190.4824.HT6
84-104-032	191.3048.Z67
84-104-048	
84-104-060	
84-104-080	

Platinum cured Silicone Single Braided Hose

BPSHP0125-C
BPSHP0188-C
BPSHP0250-C
BPSHP0375-C
BPSHP0500-C
BPSHP0625-C
BPSHP0750-C
BPSHP0875-C
BPSHP1000-C
BPSHP0125-D
BPSHP0188-D
BPSHP0250-D
BPSHP0375-D
BPSHP0500-D
BPSHP0625-D
BPSHP0750-D
BPSHP0875-D
BPSHP1000-D

Silicone Transfer Tubing

BPS-0125-0250	BPS-0375-0562
BPS-0125-0312	BPS-0375-0625
BPS-0125-0375	BPS-0500-0625
BPS-0187-0312	BPS-0500-0687
BPS-0187-0375	BPS-0500-0750
BPS-0187-0437	BPS-0625-0875
BPS-0250-0375	BPS-0625-1000
BPS-0250-0437	BPS-0750-1000
BPS-0250-0500	BPS-0750-1125
BPS-0312-0437	BPS-1000-1250
BPS-0312-0500	BPS-1000-1375
BPS-0312-0562	BPS-1000-1500
BPS-0375-0500	

Gore® STA-PURE Series PCS Loadsure	Gore® STA-PURE Series PCS Y Elements
961.0032.PFT	961.E016.K24
961.H032.PFT	961.E032.K24
961.H032.PFQ	961.E048.K24
961.M032.PFT	961.E064.K24
961.0064.PFT	961.E080.K24
961.M064.PFT	961.E080.K40
961.0096.PFT	961.E120.K40
961.0120.PFT	961.E160.K40
961.T120.SST	196.1E96.V45
961.0170.PFT	196.6E16.FP5
961.T170.SST	
961.0127.PFT	
961.0159.PFT	
961.0190.PFT	
961.0254.PFT	
189.1250.EC4	
189.1250.EJ5	
196.1120.CG5	
196.1120.DR4	
196.1120.DX5	
196.1120.GX1	
196.1120.M17	
196.1170.AC8	
196.1170.DX6	
196.1170R18	
196.1170.X14	
196.1190.GX2	
196.1190.R20	
196.1254.ED6	

Gore® STA-PURE Series PFL Loadsure [STA-PURE PFL LoadSure]	Gore® STA-PURE Series PFL Y Elements [STA-PURE PFL Y-element]
966.0032.PFT	966.E016.K24
966.M032.PFT	966.E032.K24
966.0064.PFT	966.E048.K24
966.M064.PFT	966.E064.K24
966.0096.PFT	966.E080.K24
966.T120.SST	966.E080.K40
966.T170.SST	966.E120.K40

付録 2：適合証明書（CoC）の例



Certificate of conformance

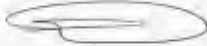
This is to certify that Watson-Marlow Pumpsil 913.A and 913.B series tubing has been manufactured at Watson-Marlow Limited, Bickland Water Road, Falmouth, UK TR11 4RU. Manufacture is in an ISO 14644-1 class 7 (class J/10,000) clean room according to cGMP principles, operating within an ISO 9001 quality system.
 Meets current USP Class VI (chapter <88>) requirements and USP <87>
 Meets ISO 10993-4, 5, 6, 10, 11 requirements
 Meets European Pharmacopoeia 3.1.9
 Meets FDA regulations 21CFR 177.2600 for food contact

Raw Material Analysis

Material Grade:	Pumpsil tubing 1.6mm bore x 1.6mm wall thickness 5m length	Lot No:	241125-645017
Specification:		Use by date (Y-M-D) :	2029.11.24
Tube Size: 1.6 mm bore 1.6 mm wall		Manufactured (Y/M/D):	2024.11.25
		Part Number:	913.AJ16.016

Test	Outcome	Lower Limit	Upper Limit
Hardness/durometer Shore A	58.1600	55.00	65.00
Elongation at break (%)	801.4800	550.00	1,500.00
Compression Set	21.5072	5.00	42.50
Specific Gravity	1.1532	1.14	2.37
Tear Strength, die B (PPI)	254.7600	200.00	500.00

The raw material used in the production of Watson-Marlow Pumpsil 913.A and 913.B series platinum-cured silicone tubing complies with the requirements of FDA 21CFR 177.2600 and USP Class VI. Further tests (as detailed in the validation pack) have been carried out on the finished product. Pumpsil tubing, and the plastic packaging in immediate contact with it, is entirely free of any animal products or by-products. The lot number and use-by date of the tubing is included on the tube, the bag and box labels.
 Tubing should be stored under dry conditions away from direct sunlight, and between -10C and 40C (14F and 104F). Wherever possible, original packaging should be retained. The performance cannot be assured for product stored outside of these conditions.



Sam Clarke, Quality & Compliance Manager

2024-12-03

This is to certify that the above designated material complies with the stated specifications when supplied in the original packaging.

For further information contact your local Watson-Marlow representative.

For contact details visit our website: www.wmfts.com

Watson-Marlow Fluid Technology Solutions has an ISO 14644-1 class 7 clean room for the manufacture of Pumpsil tubing. For further information contact your local Watson-Marlow representative.

Watson-Marlow Pump Series: Pumpsil Series: Pumpsil 913.A, 913.B, 913.C, 913.D, 913.E, 913.F, 913.G, 913.H, 913.I, 913.J, 913.K, 913.L, 913.M, 913.N, 913.O, 913.P, 913.Q, 913.R, 913.S, 913.T, 913.U, 913.V, 913.W, 913.X, 913.Y, 913.Z, 913.AA, 913.AB, 913.AC, 913.AD, 913.AE, 913.AF, 913.AG, 913.AH, 913.AI, 913.AJ, 913.AK, 913.AL, 913.AM, 913.AN, 913.AO, 913.AP, 913.AQ, 913.AR, 913.AT, 913.AU, 913.AV, 913.AW, 913.AX, 913.AY, 913.AZ, 913.BA, 913.BB, 913.BC, 913.BD, 913.BE, 913.BF, 913.BG, 913.BH, 913.BI, 913.BJ, 913.BK, 913.BL, 913.BM, 913.BN, 913.BO, 913.BP, 913.BQ, 913.BR, 913.BT, 913.BU, 913.BV, 913.BW, 913.BX, 913.BY, 913.BZ, 913.CA, 913.CB, 913.CC, 913.CD, 913.CE, 913.CF, 913.CG, 913.CH, 913.CI, 913.CJ, 913.CK, 913.CL, 913.CM, 913.CN, 913.CO, 913.CP, 913.CQ, 913.CR, 913.CT, 913.CU, 913.CV, 913.CW, 913.CX, 913.CY, 913.CZ, 913.DA, 913.DB, 913.DC, 913.DD, 913.DE, 913.DF, 913.DG, 913.DH, 913.DI, 913.DJ, 913.DK, 913.DL, 913.DM, 913.DN, 913.DO, 913.DP, 913.DQ, 913.DR, 913.DT, 913.DU, 913.DV, 913.DW, 913.DX, 913.DY, 913.DZ, 913.EA, 913.EB, 913.EC, 913.ED, 913.EE, 913.EF, 913.EG, 913.EH, 913.EI, 913.EJ, 913.EK, 913.EL, 913.EM, 913.EN, 913.EO, 913.EP, 913.EQ, 913.ER, 913.ET, 913.EU, 913.EV, 913.EW, 913.EX, 913.EY, 913.EZ, 913.FA, 913.FB, 913.FC, 913.FD, 913.FE, 913.FF, 913.FG, 913.FH, 913.FI, 913.FJ, 913.FK, 913.FL, 913.FM, 913.FN, 913.FO, 913.FP, 913.FQ, 913.FR, 913.ET, 913.FU, 913.FV, 913.FW, 913.FX, 913.FY, 913.FZ, 913.GA, 913.GB, 913.GC, 913.GD, 913.GE, 913.GF, 913.GG, 913.GH, 913.GI, 913.GJ, 913.GK, 913.GL, 913.GM, 913.GN, 913.GO, 913.GP, 913.GQ, 913.GR, 913.GT, 913.GU, 913.GV, 913.GW, 913.GX, 913.GY, 913.GZ, 913.HA, 913.HB, 913.HC, 913.HD, 913.HE, 913.HF, 913.HG, 913.HH, 913.HI, 913.HJ, 913.HK, 913.HL, 913.HM, 913.HN, 913.HO, 913.HP, 913.HQ, 913.HR, 913.HT, 913.HU, 913.HV, 913.HW, 913.HX, 913.HY, 913.HZ, 913.IA, 913.IB, 913.IC, 913.ID, 913.IE, 913.IF, 913.IG, 913.IH, 913.II, 913.IJ, 913.IK, 913.IL, 913.IM, 913.IN, 913.IO, 913.IP, 913.IQ, 913.IR, 913.IT, 913.IU, 913.IV, 913.IW, 913.IX, 913.IY, 913.IZ, 913.JA, 913.JB, 913.JC, 913.JD, 913.JE, 913.JF, 913.JG, 913.JH, 913.JI, 913.JJ, 913.JK, 913.JL, 913.JM, 913.JN, 913.JO, 913.JP, 913.JQ, 913.JR, 913.JT, 913.JU, 913.JV, 913.JW, 913.JX, 913.JY, 913.JZ, 913.KA, 913.KB, 913.KC, 913.KD, 913.KE, 913.KF, 913.KG, 913.KH, 913.KI, 913.KJ, 913.KK, 913.KL, 913.KM, 913.KN, 913.KO, 913.KP, 913.KQ, 913.KR, 913.KT, 913.KU, 913.KV, 913.KW, 913.KX, 913.KY, 913.KZ, 913.LA, 913.LB, 913.LC, 913.LD, 913.LE, 913.LF, 913.LG, 913.LH, 913.LI, 913.LJ, 913.LK, 913.LL, 913.LM, 913.LN, 913.LO, 913.LP, 913.LQ, 913.LR, 913.LT, 913.LU, 913.LV, 913.LW, 913.LX, 913.LY, 913.LZ, 913.MA, 913.MB, 913.MC, 913.MD, 913.ME, 913.MF, 913.MG, 913.MH, 913.MI, 913.MJ, 913.MK, 913.ML, 913.MM, 913.MN, 913.MO, 913.MP, 913.MQ, 913.MR, 913.MT, 913.MU, 913.MV, 913.MW, 913.MX, 913.MY, 913.MZ, 913.NA, 913.NB, 913.NC, 913.ND, 913.NE, 913.NF, 913.NG, 913.NH, 913.NI, 913.NJ, 913.NK, 913.NL, 913.NM, 913.NN, 913.NO, 913.NP, 913.NQ, 913.NR, 913.NT, 913.NU, 913.NV, 913.NW, 913.NX, 913.NY, 913.NZ, 913.OA, 913.OB, 913.OC, 913.OD, 913.OE, 913.OF, 913.OG, 913.OH, 913.OI, 913.OJ, 913.OK, 913.OL, 913.OM, 913.ON, 913.OO, 913.OP, 913.OQ, 913.OT, 913.OU, 913.OV, 913.OW, 913.OX, 913.OY, 913.OZ, 913.PA, 913.PB, 913.PC, 913.PD, 913.PE, 913.PF, 913.PG, 913.PH, 913.PI, 913.PJ, 913.PK, 913.PL, 913.PM, 913.PN, 913.PO, 913.PP, 913.PQ, 913.PR, 913.PT, 913.PU, 913.PV, 913.PW, 913.PX, 913.PY, 913.PZ, 913.QA, 913.QB, 913.QC, 913.QD, 913.QE, 913.QF, 913.QG, 913.QH, 913.QI, 913.QJ, 913.QK, 913.QL, 913.QM, 913.QN, 913.QO, 913.QP, 913.QQ, 913.QR, 913.QU, 913.QV, 913.QW, 913.QX, 913.QY, 913.QZ, 913.RA, 913.RB, 913.RC, 913.RD, 913.RE, 913.RF, 913.RG, 913.RH, 913.RI, 913.RJ, 913.RK, 913.RL, 913.RM, 913.RN, 913.RO, 913.RP, 913.RQ, 913.RR, 913.RT, 913.RU, 913.RV, 913.RW, 913.RX, 913.RY, 913.RZ, 913.SA, 913.SB, 913.SC, 913.SD, 913.SE, 913.SF, 913.SG, 913.SH, 913.SI, 913.SJ, 913.SK, 913.SL, 913.SM, 913.SN, 913.SO, 913.SP, 913.SQ, 913.SR, 913.ST, 913.SU, 913.SV, 913.SW, 913.SX, 913.SY, 913.SZ, 913.TA, 913.TB, 913.TC, 913.TD, 913.TE, 913.TF, 913.TG, 913.TH, 913.TI, 913.TJ, 913.TK, 913.TL, 913.TM, 913.TN, 913.TO, 913.TP, 913.TQ, 913.TR, 913.TT, 913.TU, 913.TV, 913.TW, 913.TX, 913.TY, 913.TZ, 913.UA, 913.UB, 913.UC, 913.UD, 913.UE, 913.UF, 913.UG, 913.UH, 913.UI, 913.UJ, 913.UK, 913.UL, 913.UM, 913.UN, 913.UO, 913.UP, 913.UQ, 913.UR, 913.UT, 913.UU, 913.UV, 913.UW, 913.UX, 913.UY, 913.UZ, 913.VA, 913.VB, 913.VC, 913.VD, 913.VE, 913.VF, 913.VG, 913.VH, 913.VI, 913.VJ, 913.VK, 913.VL, 913.VM, 913.VN, 913.VO, 913.VP, 913.VQ, 913.VR, 913.VT, 913.VU, 913.VV, 913.VW, 913.VX, 913.VY, 913.VZ, 913.WA, 913.WB, 913.WC, 913.WD, 913.WE, 913.WF, 913.WG, 913.WH, 913.WI, 913.WJ, 913.WK, 913.WL, 913.WM, 913.WN, 913.WO, 913.WP, 913.WQ, 913.WR, 913.WT, 913.WU, 913.WV, 913.WW, 913.WX, 913.WY, 913.WZ, 913.XA, 913.XB, 913.XC, 913.XD, 913.XE, 913.XF, 913.XG, 913.XH, 913.XI, 913.XJ, 913.XK, 913.XL, 913.XM, 913.XN, 913.XO, 913.XP, 913.XQ, 913.XR, 913.XT, 913.XU, 913.XV, 913.XW, 913.XX, 913.XY, 913.XZ, 913.YA, 913.YB, 913.YC, 913.YD, 913.YE, 913.YF, 913.YG, 913.YH, 913.YI, 913.YJ, 913.YK, 913.YL, 913.YM, 913.YN, 913.YO, 913.YP, 913.YQ, 913.YR, 913.YT, 913.YU, 913.YV, 913.YW, 913.YX, 913.YZ, 913.ZA, 913.ZB, 913.ZC, 913.ZD, 913.ZE, 913.ZF, 913.ZG, 913.ZH, 913.ZI, 913.ZJ, 913.ZK, 913.ZL, 913.ZM, 913.ZN, 913.ZO, 913.ZP, 913.ZQ, 913.ZR, 913.ZT, 913.ZU, 913.ZV, 913.ZW, 913.ZX, 913.ZY, 913.ZZ

図 1a 現在の Pumpsil CoC の例



Certificate of conformance

Part Number	913.A127.PFT
Description	720 Loadsure Pumpsil 12.7mm Tri-Clamp Element
Lot No	844778
Use by date (Y-M-D)	2029.05.13
Manufactured (Y-M-D)	2024.11.26
Tubing Material	Pumpsil platinum-cured silicone
Connector Material	PVDF
Storage conditions	Keep away from direct sunlight Store between -10°C and 40°C (14°F and 104°F) Original packaging should be retained. The performance cannot be assured for product stored outside of these conditions.
Site of Manufacture	Watson-Marlow Limited, Bickland Water Road, Falmouth, UK. TR11 4RU
Manufactured in Clean-Room	ISO 14644-1 class 7 (at rest) (class J/10,000) clean room according to cGMP principles
Quality System	ISO9001

Tubing Certification
USP Class VI, USP <88> Biological Reactivity tests, in vivo (70°C) USP <87> ISO 10293-4, 5, 6, 10, 11 European Pharmacopoeia 3.1.9 and USP <381> (EC) No. 1935/2004 FDA 21CFR 177.2600 ((rubber articles intended for repeated use)
Connector Certification
USP Class VI, USP <88> Biological Reactivity tests, In Vivo (70°C) (EC) No. 1935/2004 Raw material complies with: FDA 21CFR 177.2510 for food contact
Material Origin
ADCF, BSE/TSE free including packaging in immediate contact

Sams Signature here

Sam Clarke
Quality and Compliance Manager
2024.11.25
Content Revision - 3
Traceable ref - 17-QMS-FRM-000075

Date of last review - Jan 2026

For contact details visit our website: www.wmfts.com

Watson-Marlow Fluid Technology Solutions has ten world-class factories and direct sales operations in 33 countries around the globe. Providing additional local expertise are experienced distributors in over 50 countries.

Watson-Marlow Pumps, Watson-Marlow Control, Smolair, Atlas, Pumpsil, Microline, Solstice, MEDICID, FlowGuard, Atlas

図 1b 新しい Pumpsil CoC の例



Certificate of conformance

Watson-Marlow certifies that this Pumpsil platinum-cured silicone tubing element with PVDF Tri-Clamp connectors meets the specifications described and has been manufactured in an ISO 9001 facility.

Material Grade:	913.A127.PFT	Tube Part:	MR3068T
Lot No:	644778	Tube Lot:	241126-645797
Manufactured (Y/M/D):	2024/11/26	Connector Part:	MR2217M
Use by date (Y-M-D) :	2029/05/13	Connector Lot:	56374

Tube Size: 12.7 mm bore 4.8 mm wall

The Pumpsil tubing used in the production of this element has been manufactured at Watson-Marlow Limited, Bickland Water Road, Falmouth, UK TR11 4RU. Manufacture is in an ISO 14644-1 class 7 (class J/10,000) clean room according to cGMP principles, operating within an ISO 9001 quality system.
 Meets current USP Class VI (chapter <88>) requirements and USP <87>
 Meets ISO 10993-4, 5, 6, 10, 11 requirements
 Meets European Pharmacopoeia 3.1.9
 Meets FDA regulations 21CFR 177.2600 for food contact

The PVDF connectors are injection moulded from Solef 1008 PVDF that is compliant with the following standards:
 Meets USP Class VI requirements
 Meets FDA regulations 21CFR 177.2510 for food contact

Elements should be stored under dry conditions away from direct sunlight, and between -10°C and 40°C (14°F and 104°F). Wherever possible, original packaging should be retained.
 Watson-Marlow Pumpsil 913.A series tubing elements including connectors and the plastic packaging in immediate contact with it, are entirely free of any animal products or by-products. No animal products or by-products are used in the production of Watson-Marlow Pumpsil 913.A series tubing elements.



Sam Clarke, Quality & Compliance Manager

This is to certify that the above designated material complies with the stated specifications when supplied in the original packaging.
 For further information contact your local Watson-Marlow representative.

2024-11-26

Content revision: 2

For contact details visit our website: www.wmfts.com

Watson-Marlow Fluid Technology Solutions is a division of Spirax-Sarco Engineering plc. The company is a public limited company registered in England. The company is a member of the FTSE 100. The company is a member of the FTSE 100. The company is a member of the FTSE 100.

図 2a 現在の Pumpsil LoadSure CoC の例



Certificate of conformance

Part Number	913.A127.PFT
Description	720 Loadsure Pumpsil 12.7mm Tri-Clamp Element
Lot No	644778
Use by date (Y-M-D)	2029.05.13
Manufactured (Y-M-D)	2024.11.26
Tubing Material	Pumpsil platinum-cured silicone
Connector Material	PVDF
Storage conditions	Keep away from direct sunlight Store between -10°C and 40°C (14°F and 104°F) Original packaging should be retained. The performance cannot be assured for product stored outside of these conditions.
Site of Manufacture	Watson-Marlow Limited, Bickland Water Road, Falmouth, UK TR11 4RU
Manufactured in Clean-Room	ISO 14644-1 class 7 (at rest) (class J/10,000) clean room according to cGMP principles
Quality System	ISO9001

Tubing Certification	
USP Class VI, USP<88> Biological Reactivity tests, In Vivo (70°C)	
USP<87>	
ISO 10993-4, 5, 6, 10, 11 requirements.	
European Pharmacopoeia 3.1.9 and USP <381>	
FDA 21CFR 177.2600 (aqueous food)	
Connector Certification	
USP<87>	
ISO 10993-5	
Material Origin	
ADCF, BSE/TSE free including packaging in immediate contact	

Sams Signature here

Sam Clarke
Quality and Compliance Manager
2024.11.25

Content Revision – 4
Trackwise ref - 17-QMS-FRM-000075

Date of last review – Jan 2026

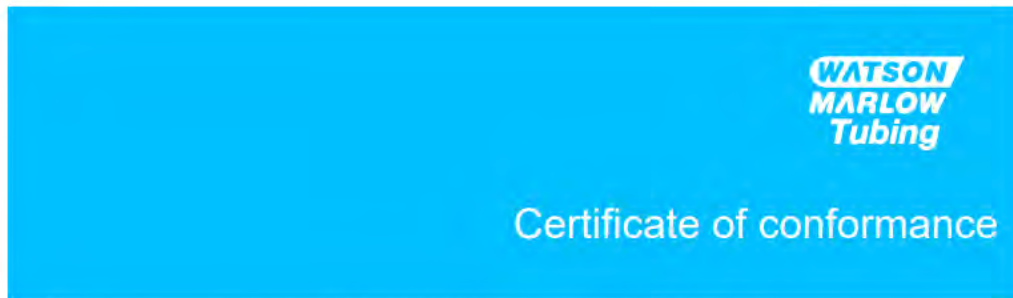
For contact details visit our website:

www.wmfts.com

Watson-Marlow Fluid Technology Solutions has ten world-class factories and direct sales operations in 33 countries around the globe. Providing additional local expertise are experienced distributors in over 50 countries.

Watson-Marlow Pumps Watson-Marlow Tubing Biotech Atrial Precision Manifolds BioPure ASEPICO FlowControl Atrial

図 2b 新しい Pumpsil LoadSure CoC の例



Watson-Marlow certifies that this STA-PURE PCS tubing element with PVDF Tri-Clamp connectors meets the specifications described and has been manufactured in an ISO 9001 facility.

Material Grade:	961.0120.PFT	Tube Part:	961.0120.040
Lot No:	654604	Tube Lot:	B23801652103
Manufactured (Y/M/D):	2025/02/26	Connector Part:	MR2217M
Use by date (Y-M-D) :	2028/12/01	Connector Lot:	2/A PQ

Tube Size: 12.0 mm bore 4.0 mm wall

The tubing used in the production of this element is a product of polytetrafluoroethylene (PTFE) and platinum addition cure silicone rubber. No peroxide curing agents are used in the formulation. Samples of the tubing lot were sent to an independent laboratory(ies) (using GLP practices - Code of Regulations 21, Part 58) to undergo USP Class VI testing and cytotoxicity testing and were rated as passing in all cases. The test records are retained on record.

The PVDF connectors are injection moulded from Solef 1008 PVDF that is compliant with the following standards:

Meets current USP Class VI requirements
Meets FDA regulations 21CFR 177.2510 for food contact

The expiration date of the element is four years from the date of manufacture of the tubing component, and this date will be less than four years of the element assembly date. This expiration date is based upon an accelerated ageing study to simulate storage of the product for four years at 23°C (73°F).

Whenever possible, original packaging should be retained. Stock should be rotated on a first in, first out basis. STA-PURE PCS tubing elements including connectors and the plastic packaging in immediate contact with it are entirely free of any animal products or by-products. No animal products or by-products are used in the production of STA-PURE PCS tubing elements.

Sam Clarke, Quality & Compliance Manager

2025-02-26

This is to certify that the above designated material complies with the stated specifications when supplied in the original packaging.

For further information contact your local Watson-Marlow representative.

Content revision 3

For contact details visit our website:

www.wmfts.com

Watson-Marlow Fluid Technology Solutions has ten world-class factories and direct sales operations in 33 countries around the globe. Providing additional local expertise are experienced distributors in over 50 countries.

Watson-Marlow Pumps Watson-Marlow Tubing Bredel Atlas Flexicon MassSine BioPure ASEPICO FlowSmart Atlas

図 3a 現在の Gore STA PURE PCS LoadSure CoC の例



Certificate of conformance

Part Number	961.0120.PFT
Description	620 LoadSure STA-PURE PCS 12mm tri-clamp element
Lot No	644778
Use by date (Y-M-D)	2029.05.13
Manufactured (Y-M-D)	2024.11.26
Tubing Material	STA-PURE PCS
Connector Material	PVDF
Storage conditions	Keep away from direct sunlight Store between -10°C and 40°C (14°F and 104°F) Original packaging should be retained. The performance cannot be assured for product stored outside of these conditions.
Site of Manufacture	Watson-Marlow Limited, Bickland Water Road, Falmouth, UK TR11 4RU
Manufactured in Clean-Room	ISO 14644-1 class 7 (at rest) (class J/10,000) clean room according to cGMP principles
Quality System	ISO9001

Tubing Certification
USP Class VI, USP<88> Biological Reactivity tests, <i>in vivo</i> (70°C) USP <87>
Connector Certification
USP <87> ISO 10993-5 USP Class VI, USP<88> Biological Reactivity tests, <i>In Vivo</i> (70°C) Raw material complies with FDA 21CFR 177.2510 for food contact
Material Origin
ADCF, BSE/TSE free including primary packaging

Sams Signature here

Sam Clarke
Quality and Compliance Manager
2024.11.25
Content Revision - 4
Trackwise ref - 17-QMS-FRM-000077

Date of last review - Jan 2026

For contact details visit our website:

www.wmfts.com

Watson-Marlow Fluid Technology Solutions has ten world-class factories and direct sales operations in 33 countries around the globe. Providing additional local expertise are experienced distributors in over 50 countries.

Watson-Marlow Pumps Watson-Marlow Tubing Swivel Adapters Peristaltic Pumps Sterile BioPure ASEPDS FlowDirect Adapters

図 3b 新しい Gore STA PURE PCS LoadSure CoC Falmouth の例



Certificate of conformance

Part Number	961.0120.PFT
Description	620 LoadSure STA-PURE PCS 12mm tri-clamp element
Lot No	644778
Use by date (Y-M-D)	2029.05.13
Manufactured (Y-M-D)	2024.11.26
Tubing Material	STA-PURE PCS
Connector Material	PVDF
Storage conditions	Keep away from direct sunlight Store between -10°C and 40°C (14°F and 104°F) Original packaging should be retained. The performance cannot be assured for product stored outside of these conditions.
Site of Manufacture	Watson-Marlow America Manufacturing Inc 16 Bulge Road, Devens, MA 01434, USA
Manufactured in Clean-Room	ISO 14644-1 class 7 (at rest) (class J/10,000) clean room according to cGMP principles
Quality System	ISO9001
Tubing Certification	
USP Class VI, USP<88> Biological Reactivity tests, <i>in vivo</i> (70°C)	
USP <87>	
Connector Certification	
USP <87>	
ISO 10993-5	
USP Class VI, USP<88> Biological Reactivity tests, <i>In Vivo</i> (70°C)	
Raw material complies with	
FDA 21CFR 177.2510 for food contact	
Material Origin	
ADCF, BSE/TSE free including primary packaging	

Grace's Signature here

Grace Muvirimi
Quality and Compliance Manager
2024.11.25
Content Revision – 4
Trackwise ref - 17-QMS-FRM-000077

Date of last review – Jan 2026

For contact details visit our website:

www.wmfts.com

Watson-Marlow Fluid Technology Solutions has ten world-class factories and direct sales operations in 33 countries around the globe. Providing additional local expertise are experienced distributors in over 50 countries.

Watson-Marlow Pumping Watson-Marlow Tubing Bristol Alpha Fluidics BlueGene BioPure ASDPCO FoodChem Alfa

図 3c 新しい Gore STA PURE PCS LoadSure CoC Falmouth の例



Certificate of Conformance

Product name:	BioPure Silicone Tubing 0.375" x 0.562" (9.6 x 14.3mm)-100'
Compound / Material:	FS-SILPLAT-13-1
Part Number:	BPS-0375-0562-100
Lot No:	0004216
Manufactured (Y/M/D):	2025-09-16
Use by date (Y-M-D) :	2030-09-15

The aforementioned products are manufactured in an ISO14644-1 Class 7 cleanroom at the Devens, MA, USA facility operating an ISO 9001 quality management system.

During qualification studies, a representative sample was tested and complies with the requirements of USP 88 Class VI, USP 87, EP 3.1.9 and ISO 10993-5,6,10,11. The material used is Animal Derived Component Free (ADCF) and complies with FDA regulations 21 CFR 177.2600.

The tubing should be stored under dry conditions away from direct sunlight and between -10°C and 40°C (14°F and 104°F). Wherever possible, original packaging should be retained. Stock should be rotated on a first in first out (FIFO) basis. The performance of these products beyond their expiry date, or that have not been stored according to recommendations outlined above cannot be assured.

Watson-Marlow America Manufacturing, Inc. certifies that this product has been released in accordance with documented manufacturing and quality assurance procedures.

Quality Representative Signature



For contact details visit our website:

www.wmftg.com

The Watson-Marlow Fluid Technology Group has ten world class factories and direct sales operations in 53 countries around the globe. Providing additional local expertise are experienced distributors in over 50 countries.

Watson-Marlow Pumps, Watson-Marlow Tubing, Stedil, Atlas, Peacock, MacSim, BioPure, ASEPCO, PicoSmart, Altra

図 4a 現在のシリコン製トランスファータブ CoC の例



Certificate of conformance

Part Number	BPS-0375-0562-100
Description	Silicone Tubing 0.375" x 0.562" (9.6 x 14.3mm) 100'
Lot No	000426
Use by date (Y-M-D)	2030.09.16
Manufactured (Y-M-D)	2025.09.15
Tube Size	9.6 mm Bore 2.4mm Wall
Material of construction	Platinum-cured silicone
Storage conditions	Keep away from direct sunlight Store between -10°C and 40°C (14°F and 104°F) Original packaging should be retained. The performance cannot be assured for product stored outside of these conditions.
Site of Manufacture	Watson-Marlow America Manufacturing Inc, Devens, MA USA
Manufactured in Clean-Room	ISO 14644-1 class 7 (at rest) (class J/10,000) clean room according to cGMP principles
Quality System	ISO9001

Certification	
USP Class VI, USP <88> (121°C)	
USP <87>	
ISO 10993-4, 5, 6, 10, 11	
European Pharmacopoeia 3.1.9	
Raw material complies with- FDA 21CFR 177.2600 (rubber articles intended for repeated use)	
ADCF, BSE/TSE free including primary packaging	
Refer to validation pack for more information	

Grace Signature here

Grace Tapiwa Muirimi
Quality and Compliance Manager
2024.11.25
Content Revision – 1
Trackwise ref - 06-QMS-FRM-000039

Date of last review – Jan 2026

For contact details visit our website:

www.wmfts.com

Watson-Marlow Fluid Technology Solutions has ten world-class factories and direct sales operations in 33 countries around the globe. Providing additional local expertise are experienced distributors in over 50 countries.

Watson-Marlow Pumping Watson-Marlow Tubing Special Alloys Polymers Medical Devices Surface ASEP/CD Resistant Alloys

図 4b 新しいシリコン製トランスファータブ CoC の例



Certificate of Conformance

Product name:	Biopure 4.8mm ID Pt Silicone Single Braided Hose (15.2m)
Compound / Material:	FS-SILPLAT-16
Part Number:	BPSHP0188-D
Lot No:	0004205
Manufactured (Y/M/D):	2025-09-02
Use by date (Y-M-D) :	2030-09-01

The aforementioned products are manufactured in an ISO14644 Class 7 cleanroom at Watson-Marlow America Manufacturing, Inc. Devens, MA, a facility operating an ISO9001 quality management system.

During qualification studies, samples of the final article have been tested to and comply with the requirements of USP 39 NF 34 <88>, E.P 3.1.9 and ISO 10993. Further details on these and additional tests may be found in the validation guide. The materials used are Animal Derived Content Free (ADCF) and comply with FDA regulations CFR 21 177.2600.

The hoses should be stored under dry conditions away from direct sunlight and between -10C and 40C (14F and 104F). Wherever possible, original packaging should be retained. Stock should be rotated on a first in first out (FIFO) basis. The performance of these products beyond their expiry date, or that have not been stored according to recommendations outlined above, cannot be assured.

Watson-Marlow America Manufacturing, Inc. certifies that this product has been released in accordance with documented manufacturing and quality assurance procedures.
Quality Representative Signature



For contact details visit our website:

www.wmftg.com

The Watson-Marlow Fluid Technology Group has ten world class factories and direct sales operations in 33 countries around the globe. Providing additional local expertise are experienced distributors in over 60 countries.

Watson-Marlow Pumps, Watson-Marlow Soling, Bruckel, Atlas, Flexcon, Metosink, BioPure, ASPECO, Farnsworth, Atlas.

図 5a 現在の編組ホース CoC の例



Certificate of conformance

Part Number	BPSHP0188-D
Description	Biopure 4.8mm ID Pt Silicone Single Braided Hose (15.2m)
	0004205
Use by date (Y-M-D)	2030.09.02
Manufactured (Y-M-D)	2025.09.01
Tube Size	4.8 mm Bore 2.2 mm Wall
Material of construction	Platinum-cured silicone
Storage conditions	Keep away from direct sunlight store between -10°C and 40°C (14°F and 104°F) Original packaging should be retained. The performance cannot be assured for product stored outside of these conditions.
Site of Manufacture	Watson-Marlow America Manufacturing Inc, Devens, MA, USA
Manufactured in Clean-Room	ISO 14644-1 class 7 (at rest) (class J/10,000) clean room according to cGMP principles
Quality System	ISO9001

Certification
USP Class VI, USP <88> (70°C) USP <87> ISO 10993-4, 5, 6, 10, 11 European Pharmacopoeia 3.1.9
Raw material complies with- FDA 21CFR 177.2600 (rubber articles intended for repeated use)
ADCF, BSE/TSE free including primary packaging
Refer to validation pack for more information

Grace Signature here

Grace Tapiwa Muvirimi
Quality and Compliance Manager
2024.11.25
Content Revision – 1
Trackwise ref - 06-QMS-FRM-000040

Date of last review – Jan 2026

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www.wmfts.com

Watson-Marlow Fluid Technology Solutions has ten world-class factories and direct sales operations in 33 countries around the globe. Providing additional local expertise are experienced distributors in over 50 countries.

Watson-Marlow Pumps Watson-Marlow Tubing ShredAir Axiom Precision MicroDose BioPure ASEPICO FlowControl Axiom

図 5b 新しい編組ホース CoC の例

Flexicon
Liquid Filling

Certificate of conformance

This is to certify that Accusil platinum-cured silicone tubing has been manufactured at Watson-Marlow Limited, Bickland Water Road, Falmouth, UK TR11 4RU. Manufacture is in an ISO 14644-1 class 7 (class J/10,000) clean room according to cGMP principles, operating within an ISO 9001 quality system.
Meets current USP Class VI (chapter <88>) requirements
Meets FDA regulations 21CFR 177.2600 for food contact
Meets ISO 10993-10, -11, -12, -4, -5, -6
Meets European Pharmacopoeia 3.1.9

Material Analysis

Material Grade:	Accusil - Platinum-Cured Tubing 0.8mm Bore X 1.6mm - 10m	Lot No:	251029-694259
Specification:		Use by date (Y-M-D) :	2030.10.28
Tube Size: 0.8 mm bore 1.6 mm wall		Manufactured (Y/M/D):	2025.10.29
		Part Number:	84-103-008
Test	Outcome	Lower Limit	Upper Limit
Elongation at break (%)	406.0700	300.00	650.00
Hardness/durometer Shore A	61.0400	57.00	65.00
Specific Gravity	1.1385	1.12	1.16
Compression Set	13.6800	0.00	30.00
Tear Strength (N/mm)	20.2310	15.00	30.00

The raw material used in the production of Accusil platinum-cured silicone tubing complies with the requirements of USP Class VI, FDA 21CFR177.2600, and ISO 10993. Further tests have been carried out on the finished product. Accusil tubing, and the plastic packaging in immediate contact with it, is entirely free of any animal products or by-products.
Tubing should be stored under dry conditions away from direct sunlight, and between -10C and 40C (14F and 104F). Wherever possible, original packaging should be retained. The performance cannot be assured for product stored outside of these conditions.



Sam Clarke, Quality & Compliance Manager

2025-11-12

This is to certify that the above designated material complies with the stated specifications when supplied in the original packaging.

For further information contact your local Watson-Marlow representative.

Content revision 2

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Watson-Marlow Fluid Technology Solutions has ten world-class factories and direct sales operations in 33 countries around the globe. Providing additional local expertise are experienced distributors in over 50 countries.

Watson-Marlow Biotech, Watson-Marlow Titanium, Accusil, Almac, Flexicon, Macoline, BioPur, ASEPPO, Zen-Smart, Altra

図 6a 現在の Accusil チューブ CoC の例



Certificate of conformance

Part-Number	84-103-008
Description	Accusil - Platinum-Cured-Tubing-0.8mm-bore-x-1.6mm-wall-thickness-10m-length
Lot-No	241003-636250
Use-by-date-(Y-M-D)	2029.10.02
Manufactured-(Y-M-D)	2024.10.03
Tube-Size	0.8mm-Bore-1.6mm-Wall
Material-of-construction	Platinum-cured-silicone
Storage-conditions	Keep-away-from-direct-sunlight Store-between-10°C-and-40°C-(14°F-and-104°F) Original-packaging-should-be-retained. The performance cannot be assured for product stored outside of these conditions.
Site-of-Manufacture	Watson-Marlow Limited, Rickland Water Road, Falmouth, UK TR11 4RU
Manufactured-in-Clean-Room	ISO-14644-1 class 7 (at rest) (class-1/10,000) clean-room-according-to-cGMP-principles
Quality-System	ISO9001

Certification

USP-Class-VI, USP<88> Biological Reactivity tests, in-vivo (70°C)

USP<87>

ISO-10993-4, 5, 6, 10, 11

European Pharmacopoeia 3.1.9

USP<381>

Raw material complies with-

FDA-21CFR-177.2600

ADCF, BSE/TSE free including primary packaging

Refer to validation pack for more information

Sams Signature here

Sam Clarke
Quality and Compliance Manager
2024.11.25

Content Revision - 3
Job ref - 17-QMS-FRM-000073

Date of last review - Jan 2026

For product details visit our website: www.wmfts.com

図 6b 現在の Accusil チューブ CoC の例



Certificate of conformance

This certifies that Watson-Marlow Bioprene tubing is manufactured at Watson-Marlow Limited, Bickland Water Road, Falmouth, UK TR11 4RU. Manufacture is in an ISO 14644-1 class 7 (class J/10,000) clean room according to cGMP principles, operating within an ISO 9001 quality system. Bioprene meets the requirements of USP Class VI (70C), USP<87>, and ISO 10993-4,10 tests. It also meets FDA 21CFR177.2600(e) (aqueous food). Further details on these and additional tests may be found in the validation guide. A Drug Master File (DMF) has been submitted to the FDA. The raw material used in the production of Watson-Marlow Bioprene tubing meets the requirements of USP Class VI (121C) and conforms to NSF 51. The raw material supplier asserts adherence to the EMEA 410/01 rev.3 regulations with regard to the use and processing of any animal-derived materials in the manufacture of the raw material. Watson-Marlow does not add any additional material in the manufacture of Bioprene. On-going biocompatibility assurance is provided by batch testing of both raw materials and tubing extruded from it.

Raw Material Analysis

Material Grade:	Bioprene Tubing 6.4mm Bore X 2.4mm Wall Thickness 15m	Lot No:	260119-779159
Specification:		Use by date (Y-M-D) :	2031.01.18
Tube Size: 6.4 mm bore 2.4 mm wall		Manufactured (Y/M/D):	2026.01.19
		Part Number:	933.0064.024
Test	Outcome	Lower Limit	Upper Limit
Hardness/durometer Shore A (5sec)	66.0000	62.00	68.00
Specific Gravity	0.9700	0.95	0.99
Ultimate tensile strength (psi)	884.7300	798.00	99,999.00
Elongation at break (%)	570.0000	340.00	99,999.00
Stress at 100% elongation (psi)	377.1000	276.00	435.00

The tubing part number, lot number and use-by date are included on the tubing bag and box labels. Tubing should be stored under dry conditions away from direct sunlight, and between -10C and 40C (14F and 104F). Wherever possible, original packaging should be retained. The performance cannot be assured for product stored outside of these conditions.

Sam Clarke, Quality & Compliance Manager

2026-01-31

This is to certify that the above designated material complies with the stated specifications when supplied in the original packaging.

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Content revision 3

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Watson-Marlow Pumps, Watson-Marlow Tubing, Bioprene, Alaris, Falcicon, MassFlow, BioPure, iSEP/CO FlowSmart, Alaris

図 7a 現在のバイオプレナムチューブ CoC の例



Certificate of conformance

Part Number	088.T400.E0G
Description	840 Hard Bioprene Element 40mm Bore 1250mm Long
Lot No	2709
Use by date (Y-M-D)	2030.07.15
Manufactured (Y-M-D)	2025.07.16
Tube Size	40mm Bore 12.75mm Wall
Material of construction	Thermoplastic Elastomer
Storage conditions	Keep away from direct sunlight. Store between -10°C and 40°C (14°F and 104°F) Original packaging should be retained. The performance cannot be assured for product stored outside of these conditions.
Site of Manufacture	Polyplas Extrusion Ltd, Wilden Industrial Estate Stourport-on-Severn Dy13 9JY
Quality System	ISO9001

Certification
NSF 51 listed
Raw material complies with- 21CFR177.2600 (aqueous food)
ADCF, BSE/TSE free including packaging in immediate contact

Sams Signature here
 Sam Clarke
 Quality and Compliance Manager
 2024.11.25

Content Revision - 1
Trackwise ref - 17-QMS-FRM-000084

Date of last review - Jan 2026

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Watson-Marlow Pumps Watson-Marlow Tubing Smold Alfas Precision Specialties BioPure ASPOC FlowSmart Alfa

図 7c 新しい硬質バイオペレンチューブ CoC の例



Certificate of conformance

Part Number	942.0127.048
Description	Pureweld tubing 12.7mm bore x 4.8mm wall thickness 15m length
Lot No	240327-600319
Use by date (Y-M-D)	2029.03.26
Manufactured (Y-M-D)	2024.03.27
Tube Size	12.7mm Bore 4.8mm Wall
Material of construction	Thermoplastic elastomer (TPE)
Storage conditions	Keep away from direct sunlight Store between -10°C and 40°C (14°F and 104°F) Original packaging should be retained. The performance cannot be assured for product stored outside of these conditions.
Site of Manufacture	Watson-Marlow Limited, Bickland Water Road, Falmouth, UK TR11 4RU
Manufactured in Clean-Room	ISO 14644-1 class 7 (at rest) (class J/10,000) clean room according to cGMP principles
Quality System	ISO9001

Certification	
USP Class VI, USP<88> Biological Reactivity tests, <i>in vivo</i> (70°C)	
USP <87>	
ISO 10993-4, 5, 6, 10, 11	
(EC) No. 1935/2004	
Raw material complies with-	
FDA regulations 21CFR 177.1810	
ADCF, BSE/TSE free including primary packaging	
Refer to validation pack for more information	

Sams Signature here

Sam Clarke
Quality and Compliance Manager
2024.11.25

Content Revision – 3
Trackwise ref - 17-QMS-FRM-000072

Date of last review – Jan 2026

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Watson-Marlow Plunger Watson-Marlow Tubing Syringe Admix Peristaltic Manifold BioPure ASEPPO Florentium Kilo

図 8b 新しい PureWeldXL チューブ CoC の例

**WATSON
MARLOW
Tubing**

Certificate of conformance

This is to certify that Watson-Marlow PureWeld XL tubing has been manufactured at Watson-Marlow Limited, Bickland Water Road, Falmouth, UK TR11 4RU. Manufacture is in an ISO 14644-1 class 7 (class J/10,000) clean room according to cGMP principles, operating within an ISO 9001 quality system.
Meets current USP Class VI (chapter <88>) requirements and USP <87>
Meets FDA regulations 21CFR 177.2600 for food contact (aqueous foods)

Raw Material Analysis

Material Grade:	Pureweld XL Tubing 6.4mm Bore X 2.4mm Wall Thickness	Lot No:	251006-691832
Specification:		Use by date (Y-M-D) :	2030.10.05
		Manufactured (Y/M/D):	2025.10.06
Tube Size: 6.4 mm bore 2.4 mm wall		Part Number:	942.0064.024
Test	Outcome	Lower Limit	Upper Limit
Hardness/durometer Shore A 3s	68.0000	67.00	73.00
Elongation at break (%)	749.0000	420.00	99,999.00
Density/Specific Gravity	0.8900	0.85	0.95
Compression Set	26.0000	0.00	80.00
Stress at 100% elongation (MPa)	2.9000	2.00	4.00
Tear Strength (kN/m)	36.1000	30.00	99.00

The raw material used in the production of Watson-Marlow PureWeld XL tubing complies with the requirements of USP Class VI and FDA 21CFR177.1810. Further tests as (detailed in the validation pack) have been carried out on the extruded tubing.
The tubing part number, lot number and use-by date are included on the tubing bag and box labels.
Tubing should be stored under dry conditions away from direct sunlight, and between -10C and 40C (14F and 104F). Wherever possible, original packaging should be retained. The performance cannot be assured for product stored outside of these conditions.



Sam Clarke, Quality & Compliance Manager

2025-10-08

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Content revision 2

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Watson-Marlow Fluid Technology Solutions are an established leading manufacturer and supplier of fluid handling solutions in 20 countries around the world. Providing a wide range of products and services, we are proud to be a global leader in fluid handling solutions.

図 8a 現在の PureWeldXL チューブの CoC の例



Certificate of conformance

Part Number	942.0127.048
Description	Pureweld tubing 12.7mm bore x 4.8mm wall thickness 15m length
Lot No	240327-600319
Use by date (Y-M-D)	2029.03.26
Manufactured (Y-M-D)	2024.03.27
Tube Size	12.7mm Bore 4.8mm Wall
Material of construction	Thermoplastic elastomer (TPE)
Storage conditions	Keep away from direct sunlight Store between -10°C and 40°C (14°F and 104°F) Original packaging should be retained. The performance cannot be assured for product stored outside of these conditions.
Site of Manufacture	Watson-Marlow Limited, Bickland Water Road, Falmouth, UK TR11 4RU
Manufactured in Clean-Room	ISO 14644-1 class 7 (at rest) (class J/10,000) clean room according to cGMP principles
Quality System	ISO9001

Certification

USP Class VI, USP<88> Biological Reactivity tests, *in vivo* (70°C)
USP <87>
ISO 10993-4, 5, 6, 10, 11
(EC) No. 1935/2004
Raw material complies with-
FDA regulations 21CFR 177.1810
ADCF, BSE/TSE free including primary packaging
Refer to validation pack for more information

Sams Signature here

Sam Clarke
Quality and Compliance Manager
2024.11.25

Content Revision - 3
Trackwise ref - 17-QMS-FRM-000072

Date of last review - Jan 2026

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Watson-Marlow Pumping Watson-Marlow Filling Biotek Alkox Precision Blenders BioPur Advanced FluidTech Alkox

図 8b 新しい PureWeldXL チューブ CoC の例