

Welch Allyn
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WelchAllyn

MANUFACTURER'S DECLARATION OF CONFORMITY
Made in accordance with Council Directive 93/42/EEC Annex II, Annex V, Annex VI or
Annex VII, and relating to the devices listed below or in the attached Schedule.

Reference: DOC-MDD-048, Revision 4

Manufacturer's Name: Welch Allyn, Inc.

Business Address: Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls, NY 13153-0220



Regulatory Affairs Manager – EMEA
Welch Allyn, Ltd.
Navan Business Park
Dublin Road
Navan, County Meath
Republic of Ireland

Medical Device(s): Blood Pressure Accessories

5080-01;

5082-X, where X corresponds to the following extensions: 01, 02, 03, 06, 07, 08, 11, 16, 18, 21, 22, 23, 24, 25, 26, 42, 43, 44, 45, 56, 58, 59, 61, 62, 63, 64, 65, 67, 68, 70, 71, 72, 73, 74, 75, 76, 141, 142, 143, 144, 159, 168, 188, 189, 81-1, 81-3, 81-3HP, 81-3MQ, 82-1, 82-2, 82-3, 82-4, 82-5, 82-3HP, 82-3MQ, 82-4HP, 82-4MQ, 83-1, 83-2, 83-3, 83-4, 83-5, 83-3HP, 83-4HP, 83-3MQ, 83-4MQ, 84-1, 84-2, 84-3, 84-4, 84-5, 84-3HP, 84-4HP, 84-3MQ, 84-4MQ, 84P-1, 84P-2, 84P-3, 84P-4, 84P-5, 84P-3HP, 84P-4HP, 84P-3MQ, 84P-4MQ, 85-1, 85-2, 85-3, 85-4, 85-5, 85-3HP, 85-4HP, 85-3MQ, 85-4MQ, 86-1, 86-2, 86-3, 86-4, 86-5, 86L-1, 86L-2, 86L-3, 86L-4, 86-3HP, 86-4HP, 86-3MQ, 86-4MQ, 86L-3HP, 86L-4HP, 86L-3MQ, 86L-4MQ, 87-1, 87-2, 87-3, 87-4, 87-5, 87L-1, 87L-2, 87L-3, 87L-4, 87-3HP, 87-4HP, 87-3MQ, 87-4MQ, 87L-3HP, 87L-4HP, 87L-3MQ, 87L-4MQ, 88-1, 88-2, 88-3, 88-4, 88-5, 88-3HP, 88-4HP, 88-3MQ, 88-4MQ, 91-1, 91-3, 91-3HP, 91-8HP, 91-3MQ, 91-8MQ, 91-6, 91-8, 92-1, 92-2, 92-3, 92-4, 92-5, 92-6, 92-7, 92-8, 92-9, 92-3HP, 92-4HP, 92-8HP, 92-9HP, 92-3MQ, 92-4MQ, 92-8MQ, 92-9MQ, 93-1, 93-2, 93-3, 93-4, 93-5, 93-6, 93-7, 93-8, 93-9, 93-3HP, 93-4HP, 93-8HP, 93-9HP, 93-3MQ, 93-4MQ, 93-8MQ, 93-9MQ, 94-1, 94-2, 94-3, 94-4, 94-5, 94-6, 94-7, 94-8, 94-9, 94-3HP, 94-4HP, 94-8HP, 94-9HP, 94-3MQ, 94-4MQ, 94-8MQ, 94-9MQ, 94P-1, 94P-2, 94P-3, 94P-4, 94P-5, 95-1, 95-2, 95-3, 95-4, 95-5, 95-6, 95-7, 95-8, 95-9, 95-3HP, 95-4HP, 95-8HP, 95-9HP, 95-3MQ, 95-4MQ, 95-8MQ, 95-9MQ, 96-1, 96-2, 96-3, 96-4, 96-5, 96-7, 96-8, 96-9, 96-3HP, 96-4HP, 96-8HP, 96-9HP, 96-3MQ, 96-4MQ, 96-8MQ, 96-9MQ, 96L-1, 96L-2, 96L-3, 96L-3HP, 96L-3MQ, 96L-4, 96L-4HP, 96L-4MQ, 96L-6, 96L-7, 96L-8, 96L-8HP, 96L-8MQ, 96L-9, 96L-9HP, 96L-9MQ, 97-1, 97-2, 97-3, 97-4,

97-5, 97-6, 97-8, 97-9, 97-3HP, 97-4HP, 97-8HP, 97-9HP, 97-3MQ, 97-4MQ, 97-8MQ, 97-9MQ, 97L-1, 97L-2, 97L-3, 97L-3HP, 97L-9HP, 97L-3MQ, 97L-4, 97L-4HP, 97L-4MQ, 97L-9MQ, 97L-6, 97L-7, 97L-8, 97L-8HP, 97L-8MQ, 97L-9, 98-1, 98-2, 98-3, 98-4, 98-4HP, 98-9HP, 98-4MQ, 98-9MQ, 98-5, 98-6, 98-7, 98-8, 98-9, 98-3HP, 98-8HP, 98-3MQ, 98-8MQ, 101-1, 101-2, 102-1, 102-2, 103-1, 103-2, 104-1, 104-2, 105-1, 105-2, 146, 147, 148, 149, 150, 151, 152, 153, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 173, 176, 180, 181, 182, 183, 184, 201-1, 201-3, 202-1, 202-2, 202-3, 202-4, 202-5, 203-1, 203-2, 203-3, 203-4, 203-5, 204-1, 204-2, 204-3, 204-4, 204-5, 204P-1, 204P-2, 204P-3, 204P-4, 204P-5, 205-1, 205-2, 205-3, 205-4, 205-5, 206-1, 206-2, 206-3, 206-4, 206-5, 206L-1, 206L-2, 206L-3, 206L-4, 207-1, 207-2, 207-3, 207-4, 207-5, 207L-1, 207L-2, 207L-3, 207L-4, 208-1, 208-2, 208-3, 208-4, 208-5, 211-1, 211-3, 212-1, 212-2, 212-3, 212-4, 212-5, 213-1, 213-2, 213-3, 213-4, 213-5, 214-1, 214-2, 214-3, 214-4, 214-5, 214P-1, 214P-2, 214P-5, 215-1, 215-2, 215-3, 215-4, 215-5, 216-1, 216-2, 216-3, 216-4, 216-5, 217-1, 217-2, 217-3, 217-4, 217-5, 218-1, 218-2, 218-3, 218-4, 218-5, 221-1, 222-1, 222-2, 223-1, 223-2, 224-1, 224-2, 224P-1, 225-1, 225-2, 226-1, 226-2, 226L-1, 227-1, 227-2, 227L-1, 228-1, 228-2, 231-1, 232-1, 232-6, 232-2, 233-1, 233-2, 233-6, 234-1, 234-2, 234-6, 234P-1, 235-1, 235-2, 235-6, 236-1, 236-2, 236-6, 236L-1, 236L-6, 237-1, 237-2, 237L-1, 237-6, 237L-6, 238-1, 238-2, 238-6, 241-1, 241-2, 241-3, 241-4, 241-5, 241-6, 241-7, 241-8, 241-9, 241-10, 241-17, 241-18, 241-19, 241-20, 241-3HP, 241-4HP, 241-7HP, 241-8HP, 241-3MQ, 241-4MQ, 241-7MQ and 241-8MQ;

5084-X, where X corresponds to the following extensions: 81-1, 81-3, 81-3MQ, 82-1, 82-2, 82-3, 82-3MQ, 82-4, 82-4MQ, 83-1, 83-2, 83-3, 83-3MQ, 83-4, 83-4MQ, 84-1, 84-2, 84-3, 84-3MQ, 84-4, 84-4MQ, 85-1, 85-2, 85-3, 85-3MQ, 85-4, 85-4MQ, 86-1, 86-2, 86-3, 86-3MQ, 86-4, 86-4MQ, 86L-1, 86L-2, 86L-3, 86L-3MQ, 86L-4, 86L-4MQ, 87-1, 87-2, 87-3, 87-3MQ, 87-4, 87-4MQ, 87L-1, 87L-2, 87L-3, 87L-3MQ, 87L-4, 87L-4MQ, 88-1, 88-2, 88-3, 88-3MQ, 88-4, 88-4MQ, 91-1, 91-3, 91-3MQ, 92-1, 92-2, 92-3, 92-3MQ, 92-4, 92-4MQ, 93-1, 93-2, 93-3, 93-3MQ, 93-4, 93-4MQ, 94-1, 94-2, 94-3, 94-3MQ, 94-4, 94-4MQ, 95-1, 95-2, 95-3, 95-3MQ, 95-4, 95-4MQ, 96-1, 96-2, 96-3, 96-3MQ, 96-4, 96-4MQ, 96L-1, 96L-2, 96L-3, 96L-3MQ, 96L-4, 96L-4MQ, 97-1, 97-2, 97-3, 97-3MQ, 97-4, 97-4MQ, 97L-1, 97L-2, 97L-3, 97L-3MQ, 97L-4, 97L-4MQ, 98-1, 98-2, 98-3, 98-3MQ, 98-4, 98-4MQ, 101-1, 101-2, 102-1, 102-2, 103-1, 103-2, 104-1, 104-2, 105-1 and 105-2;

5086-X, where X corresponds to the following extensions: 01, 03, 04, 05 and 06;

5087-X, where X corresponds to the following extensions: 14 and 15;

5088-X, where X corresponds to the following extensions: 01, 05, 06 and 06H;

5089-X, where X corresponds to the following extensions: 01, 01DM, 02, 03, 04, 09, 11, 12, 13, 18, 19, 21, 22, 25, 26, 30, 31, 32, 33, 34, 35, 36, 37 and 38;

5091-X, where X corresponds to the following extensions: 13, 41, 47, 48 and 62;

5097-X, where X corresponds to the following extensions: 17 and 36;

5098-79;

5200-X, where X corresponds to the following extensions: 01, 02, 03, 04, 05, 06, 07, 08, 09, 10, 11, 12, 13, 14, 15, 16, 17, 18, 25, 51, 68 and 70;

7052-X, where X corresponds to the following extensions: 35, 36 and 37.

Reuse-X where X corresponds to the following extensions: 06, 06-1HP, 06-1MQ, 06-1SC, 06-1TP, 06-1TPE, 07, 07-1HP, 07-1MQ, 07-1SC, 07-1TP, 07-1TPE, 07-2BV, 07-2BVC, 07-2MF, 07-2MQ, 07-2SC, 07-2TP, 07-2TPE, 08, 08-1HP, 08-1MQ, 08-1SC, 08-1TP, 08-1TPE, 08-2BV, 08-2BVC, 08-2FM, 08-2MQ, 08-2SC, 08-2TP, 08-2TPE, 09, 09-1HP, 09-1MQ, 09-1SC, 09-1TP, 09-1TPE, 09-2BV, 09-2BVC, 09-2BVS, 09-2MF, 09-2MQ, 09-2SC, 09-2TP, 09-2TPE, 10, 10-1HP, 10-1MQ, 10-1SC, 10-1TP, 10-1TPE, 10-2BV, 10-2BVC, 10-2MF, 10-2MQ, 10-2SC, 10-2TP, 10-2TPE, 11, 11-1HP, 11-1MQ, 11-1SC, 11-1TP, 11-1TPE, 11-2BV, 11-2BVC, 11-2MF, 11-2MQ, 11-2SC, 11-2TP, 11-2TPE, 11L, 11L-1HP, 11L-1MQ, 11L-1SC, 11L-1TP, 11L-1TPE, 11L-2BV, 11L-2BVC, 11L-2MF, 11L-2MQ, 11L-2SC, 11L-2TP, 11L-2TPE, 12, 12-1HP, 12-1MQ, 12-1SC, 12-1TP, 12-1TPE, 12-2BV, 12-2BVC, 12-2MF, 12-2MQ, 12-2SC, 12-2TP, 12-2TPE, 12L, 12L-1HP, 12L-1MQ, 12L-1SC, 12L-1TP, 12L-1TPE, 12L-2BV, 12L-2BVC, 12L-2MF, 12L-2MQ, 12L-2SC, 12L-2TP, 12L-2TPE, 13, 13-1HP, 13-1MQ, 13-1SC, 13-1TP, 13-1TPE, 13-2BV, 13-2BVC, 13-2MF, 13-2MQ, 13-2SC, 13-2TP, 13-2TPE, MLT

Soft-X where X corresponds to the following extensions: 06, 06-1HP, 06-1MQ, 06-1SC, 06-1TP, 07, 07-1HP, 07-1MQ, 07-1SC, 07-1TP, 07-2BV, 07-2BVC, 07-2MQ, 07-2SC, 07-2TP, 07-2TPE, 08, 08-1HP, 08-1MQ, 08-1SC, 08-1TP, 08-2BV, 08-2BVC, 08-2MQ, 08-2SC, 08-2TP, 08-2TPE, 09, 09-1HP, 09-1MQ, 09-1SC, 09-1TP, 09-2BV, 09-2BVC, 09-2MQ, 09-2SC, 09-2SCC, 09-2TP, 09-2TPE, 10, 10-1HP, 10-1MQ, 10-1SC, 10-1TP, 10-2BV, 10-2BVC, 10-2MQ, 10-2SC, 10-2SCC, 10-2TP, 10-2TPE, 11, 11-1HP, 11-1MQ, 11-1SC, 11-1TP, 11-2BV, 11-2BVC, 11-2MQ, 11-2SC, 11-2SCC, 11-2TP, 11-2TPE, 11L, 11L-1HP, 11L-1MQ, 11L-1SC, 11L-1TP, 11L-2BV, 11L-2BVC, 11L-2MQ, 11L-2SC, 11L-2TP, 11L-2TPE, 12, 12-1HP, 12-1MQ, 12-1SC, 12-1TP, 12-2BV, 12-2BVC, 12-2MQ, 12-2SC, 12-2TP, 12-2TPE, 12L, 12L-1HP, 12L-1MQ, 12L-1SC, 12L-1TP, 12L-1TPE, 12L-2BV, 12L-2BVC, 12L-2MF, 12L-2MQ, 12L-2SC, 12L-2TP, 12L-2TPE, 13, 13-1HP, 13-1MQ, 13-1SC, 13-1TP, 13-2BV, 13-2BVC, 13-2MQ, 13-2SC, 13-2SCC, 13-2TP, 13-2TPE, MLT

Vinyl-X where X corresponds to the following extensions: 06, 06-1HP, 06-1MQ, 06-1SC, 07, 07-1HP, 07-1MQ, 07-1SC, 07-2BV, 07-2BVC, 07-2MQ, 07-2SC, 08, 08-1HP, 08-1MQ, 08-1SC, 08-2BV, 08-2BVC, 08-2MQ, 08-2SC, 09, 09-1HP, 09-1MQ, 09-1SC, 09-2BV, 09-2BVC, 09-2MQ, 09-2SC, 10, 10-1HP, 10-1MQ, 10-1SC, 10-2BV, 10-2BVC, 10-2MQ, 10-2SC, 11, 11-1HP, 11-1MQ, 11-1SC, 11-2BV, 11-2BVC, 11-2MQ, 11-2SC, 11L, 11L-1HP, 11L-1MQ, 11L-1SC, 11L-2BV, 11L-2BVC, 11L-2MQ, 11L-2SC, 12, 12-1HP, 12-1MQ, 12-1SC, 12-2BV, 12-2BVC, 12-2MQ, 12-2SC, 12L, 12L-1HP, 12L-1MQ, 12L-1SC, 12L-2BV, 12L-2BVC, 12L-2MQ, 12L-2SC, 13, 13-1HP, 13-1MQ, 13-1SC, 13-2BV, 13-2BVC, 13-2MQ, 13-2SC, 13-2SCC, 13-2TP, 13-2TPE, MLT

1-BARB, 1-SC, 1-MQ, 1-HP, 1-TPS, 1-TPSE, 1-TPL, 1-TPLE, 2-BARB, 2-SC, 2MF, 2-SCC, 2-MQ, 2-TP, 2-TPLE, 2-TPSE, 2-SRC, 2-BVL, 2-BVLC, 2-BVS, 2-BVSC, 2-BVD, 2-BVDC, 1SRCL, 1SRCS, 1DSAL, 1DSAS, 1DSLCL, PORT-1, PORT-2, SOFTCARD, VINYL CARD

Classification:

Class I

Reference: DOC-MDD-048, Revision 4

Classification Rules: Annex IX , Rule 1

GMDN Code and Term: 34978 – Cuff, blood pressure, reusable

Scope of Application: All (see standards list below)
Except:

- FlexiPort disposable and reusable cuffs, sizes 6, 7, 8, and 9, do not comply with section 9.3a of EN 1060-1.
- EN 1060-3 applies only to FlexiPort Reuse-X, Soft-X, and Vinyl-X cuffs.

Registrar/Notified Body: Duetsche Gesellschaft zur Zertifizierung von Managementsystemen (DQS GmbH)
Notified Body Number: 0297

Quality Sys. Certificate: DQS GmbH certificate 314505 MP23 indicating conformance to DIN EN ISO 13485:2003.

Standards Applied: EN 1060-1, EN 1060-2, EN 1060-3, ISO 14971, EN 980 and EN 1041

Authorised Signatory:



Huy Doan, Regulatory Affairs Manager

8/1/07

Date