



## Declaration of Conformity

### Reusable Cables

Utah Medical Products, Inc. (UTMD), 7043 South 300 West, Midvale, Utah, U.S.A. guarantees and declares that the CE Marked products defined on the attached are in conformity with the applicable provisions of the Medical Device Regulation (EU) 2017/745. This Declaration of conformity is issued under the sole responsibility of Utah Medical Products, Inc.

This declaration is made in accordance with Annex IV of (EU) 2017/745 for a Class I device. The products covered under this Declaration of Conformity are intended to facilitate interfacing between a pressure monitoring transducer and an electronic patient monitor.

The CE Mark Products listed in this Declaration of Conformity are in compliance with the provisions of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

This declaration is supported by the Quality System certification based on the harmonized standard EN ISO 13485:2016.

This certificate is valid for all devices described herein and bearing the CE-Mark, manufactured in our site in Midvale, Utah, U.S.A. or in our Athlone Ireland site. For all devices listed below, the authorized representative in the European Community can be contacted at Utah Medical Products Ltd., Athlone Business & Technology Park, Athlone, County Westmeath N37 XK74 Ireland.

HIBC Basic UDI-DI: ++H671PMCABLES95

Declaration of Conformity issued on May 26, 2021 at Utah Medical Products, Inc. (UTMD), 7043 South 300 West, Midvale, Utah, U.S.A

  
Ben Shirley  
VP Quality Assurance

Detailed list of Reusable Cables Catalog Numbers:

Catalog Number	Description	Effective Date
650-201	Cable, MEM/TEK/SL 500, No Cal	5/28/98
650-202	Cable, HP Twinax (5 $\mu$ V/V/mmHg)	5/28/98
650-203	Cable, DRAGER 10 Pin	5/28/98
650-203-20	Cable, DRAGER 20 cm	4/25/05
650-203W	Cable, DRAGER 10 Pin, White	9/05/14
650-204	Cable, DS/IREX/Marquette/HP/Kontron	5/28/98
650-205	Cable, HP 8040A (5 $\mu$ V/V/mmHg)	5/28/98
650-206	Cable, HP (12 Pin) (5 $\mu$ V/V/mmHg)	5/28/98
650-206M	Cable, Mindray (12 Pin) (5 $\mu$ V/V/mmHg)	9/21/15
650-206-D	Cable, Philips Intellivue, Dual Pressure	6/30/17
650-207	Cable, HP 8030A (5 $\mu$ V/V/mmHg)	5/28/98
650-208	Cable, SL/TEK/VI TEK/400, 500, 600 Alpha PC	5/28/98
650-208W	Cable, SL/TEK/VI TEK/400, 500, 600 Alpha PC, White	9/05/14
650-209	Cable, SL/Alpha/700 Series	5/28/98
650-210	Cable, Siemens Sirecust 300 series	7/19/07
650-211	Cable, Marquette, 7000 and 7200 Series	5/28/98
650-212	Cable, Marquette (GE) PDS 2000 Series	5/28/98
650-213	Cable, Litton (Hellige)	5/28/98
650-214	Cable, Abbott	5/28/98
650-215	Cable, E for M, IM/OM/VR Series (No Cal)	5/28/98
650-216	Cable, Air Shields (Narco) AS8 Series	5/28/98
650-217	Cable, AS (Narco) AS100/Simonson/WEIL/Nicolay	5/28/98
650-218	Cable, Air Shields (Narco) 8000/Care/Gould	5/28/98
650-219	Cable, Corometrics 115 Fetal (Nicolay) (Deltran)	5/28/98
650-221	Cable, Fukuda Denshi	5/28/98
650-223	Cable, Honeywell CM/RM Series, Dager PM 8014 & PM 8060	5/28/98
650-224	Cable, Litton (Datamdix)/B-D Electrodyne/Viking	5/28/98
650-225	Cable, Nihon Kohden	5/28/98
650-226	Cable, Pioneer (Picker)/American Optical	5/28/98
650-227	Cable, Burdick M200 Kone (Nicolay)	5/28/98
650-229	Cable, Fetascan 1000 International Biomedics	5/28/98
650-230	Cable, Fetal Logic 4000, Kaat, K2000	5/28/98
650-231	Cable, Corometrics 115 Fetal (Nicolay), Intran	5/28/98
650-232	Cable, Microcor	5/28/98
650-233	Cable, Fukuda Denshi DS-3300/HB-300	5/28/98
650-234	Cable, Siemens Mingograph (15 Pin)	5/28/98
650-236	Cable, Marquette Tram 100-800 Series	5/28/98
650-236W	Cable, Marquette Tram 100-800 Series, White	9/05/14
650-238	Cable, Analogic, Fetal Gard 2000	5/28/98
650-239	Cable, PPG Vicom Series	5/28/98

Catalog Number	Description	Effective Date
650-240	Cable, Phillips, Avalon FM30/50	11/21/06
650-240G	Cable, Phillips, Avalon FM30 ( With grey transducer connector)	5/24/08
650-241	Cable, Fukuda Denshi DS-5000/7000 Series	11/29/07
650-242	Cable, Neoventa, Stan S21 Stan S31	11/16/10
650-243	Cable, Neoventa, Stan 5	10/30/14
650-251	Cable, PhysioControl VSM-1 (with Cal)	5/28/98
650-252	Cable, HP with Twinax	4/11/06
650-255	Cable, HP 8040A (40 $\mu$ V/V/mmHg)	5/28/98
650-256	Cable, HP 12 Pin (40 $\mu$ V/V/mmHg)	5/28/98
650-258	Cable, Spacelabs/Tek/Vitiatek 400, 500 (W/C)	5/28/98
650-263	Cable, AMS IM-76, Litton, Air Shields	5/28/98
650-265	Cable, E for M IM/OR/VR with Cal	5/28/98
650-267	Cable, HP 12 pin, 7800 Series, Merlin	4/27/06
650-298	Cable, No Monitor Connector	5/28/98
650-605	Cable, HP 8040A with Zero Button	5/28/98
650-631	Cable, Corometrics with Zero Button	5/28/98
650-640	Cable, Phillips, Avalon FM30/50, with Zero Button	8/20/09
650-299-14	Cable, Quinton Q-Cath	7/25/00
650-299-19	Cable, Cobe Perfusion	11/25/02
650-299-28	Cable, Shiley Stockert	9/17/01
650-299-36	Cable, Sarns 3M 8000 or 9000	9/28/01
650-299-40	Cable, Schiller CM8	6/30/00
650-299-42	Cable, Dantec (E) Urodyne 5000	7/24/00
650-299-46	Cable, Bard Lab Systems Plus and Clear Sign Amplifier(AmphenoI)	5/09/01
650-299-58	Criticare Scholar	6/19/06
650-299-59	Cable, PPG/Midas	6/18/01
650-299-60	Cable, Drager TC Cable Module 5700202	6/20/03
650-299-68	Cable, Reusable, Prucka GE Medical, Cardiolab II	5/07/01
650-299-72	Cable, Physiogard SM785P (Bruker)	5/24/01
650-299-78	Cable, Maquet HL20	11/26/03
650-299-83	Cable, Schwazer Cardis 5000, 5 Pin	8/09/02
650-299-87	Cable, Schwarzer Cardis 3000	8/05/05
650-299-90	Cable, Witt Biomedical Caylsto Series 3 Monitor, 4 Pin	2/17/05
650-299-91	Cable, Airshields, Burdick, Datex	4/14/05
650-299-96	Cable, Marquet HL30	6/25/08
650-299-98	Cable, Schiller BP-1000, FYSICON	8/12/08
650-299-100	Cable, Huntleigh SC1000	5/07/09
650-299-101	Cable, Cardiotek	5/28/09
650-299-105	Cable, Schwarzer	4/05/11
650-299-106	Cable, Terumo Model 8000 and Advanced Perfusion System 1	8/30/12
650-299-107	Cable, Edan, F9 Fetal Monitor, Intran	2/04/14
650-299-108	Cable, Medrad, Veris	11/25/14
650-299-111	Cable, Zoe Medical Century System VET PPM3	8/16/16

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Catalog Number	Description	Effective Date
650-299-112	Cable, Millar PCU-2000	8/16/16
650-299-114	Jumper Cable, 4 Foot, Deltran to Hirose	7/03/18
650-299-115	Cable, Neovanta STAN S41, Fetan Monitor	1/22/19
650-299-116	Cable, Seda, Mortara	3/06/19
650-299-117	Cable, Retia Argos	3/06/19
650-299-118	Cable, Jumper Female Deltran to Hirose, 20 ft	5/21/19

Additional Special Catalog Numbers (650-299-XXX) may also bear the CE Mark.

Additional cables may be CE Marked which have a letter following the base catalog number. The letter indicates that there is a color or other variation from the base number. The electrical connections of the cables with each variation are the same.

Additional cables may be CE Marked which have a dash and a D following the base number. These cables are Dual transducer (two transducers may be connected to one monitor) cables.

Cables are 11 ½ feet to 13 feet long unless indicated otherwise. A length different from the base cable will be indicated by placing a dash after the basic catalog number and placing a 2 or 3 digit extension after the dash to indicating the cable length.