

DECLARATION OF EC CONFORMITY

WE:

Name of Manufacturer: Przedsiębiorstwo Innowacyjno - Handlowe VARIA Ltd.
Manufacturer Address POLAND, 60-473 Poznan, 10 Biecka str.
SRN (Single Registration Number)

Basic UDI-DI 590307622TPAPERKTGQ6
Name of product: **Recorder Thermal Paper for CTG Devices**
Product size: aa x bb (aa x bb x cc) It depends on dimension and format type - See Annex I
Product list: See Annex II

Risk Class: Class I Rule I (MDR Annex VIII)
Quality System: ISO 13485

Conformity assessment route: P.I.H. VARIA Sp. z o.o. uses the following procedure for the CE-labeling of their products according to Regulation MDR 2017/745

We herewith declare that the mentioned products meet the Regulation of the EU MDR 2017/745 for medical devices.

This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Signed for and on behalf of:

P.I.H.VARIA Sp. z o.o.

WICEPREZES

mgr inż. Jacek Witaszek

Jacek Witaszek
Vice-President

Poznan, 25-05-2021

Rev A25052025v1.0.0

ANNEX I to the Declaration of Conformity

aa x bb means size of roll paper: aa - width of the roll, bb - length of the roll

aa x bb x cc means size of Z - fold paper: aa - width of sheet, bb - length of sheet, cc - number of sheets in Z - fold

ANNEX II to the Declaration of Conformity

Device name	Index number	Device model	Dimentions /
			A (mm) x B (m)
			/ x C (z-fold)
Biocare	T5Z112100150R001	BIOCARE FM-801 scale FHR 60 - 210 bpm	112x100x150
Bionet 4 P.d.	T5R15225116R0001	Fetalcare FC-1400 scale FHR 50 - 210 bpm	152x25
	T5R21520115R0004	Fetalcare FC-700 scale FHR 50 - 240 bpm	215x20
Biosys	T5Z112120250B004	BFM-800 scale FHR 50 - 240 bpm	112x120x250
	T5R11225E12R0KTG	BFM-900 scale FHR 50 - 210/240 bpm	112x25
	T5Z120120150B004	IFM-500 scale FHR 50 - 240 bpm	120x120x150
Bistos 3 P.d.	T5Z130120250R000	BT-300 scale FHR 60 - 210/240 bpm	130x120x250
	T5Z152090160R004	BT350 scale FHR 30 - 240 bpm	152x90x160
Brael 10 P.d.	T5R11020E12O0000	BFM-10	110x20
Comen 1 P.d.	T5Z112090150R001	Star 5000/5000C; scale FHR 30 - 210 bpm	112x90x150
	T5Z112100150A004	Star 5000E; scale FHR 30 - 240 bpm	112x100x150
	T5Z151090150A004	Star 5000D/F C21/22; scale FHR 30 - 240 bpm	151x90x150
Contec	T5Z112100150RM04	CMS800G/G1; scale FHR 30 - 240 bpm	112x100x150
Corometrics	T5Z152090160R004	4305AAO scale FHR 30 - 240 bpm	152x90x160
	T5Z152090150R001	4305BAO scale FHR 50 - 210 bpm	152x90x150
Econet	T5R11225E12R0KTG	BFM-900 scale FHR 50 - 210/240 bpm	112x25
	T5R11225E12R0KTG	Insight scale FHR 50 - 210/240 bpm	112x25
	T5Z152090160R004	Ecotwin scale FHR 30 - 240 bpm	152x90x150
Edan 2 P.d.	T5Z112090150RM01	Cadence / scale FHR 50 - 210 bpm	112x90x150
	T5Z112090150RM04	Cadence / scale FHR 30 - 240 bpm	112x90x150
	T5Z152090160R004	F3 / F6 / F9 Express scale FHR 30 - 240 bpm	152x90x160
	T5Z150100150VM00	F2 scale FHR 50 - 210 bpm	150x100x150
Goldway	T5Z111100150R001	UT-3000 scale FHR 30 - 210 bpm	111x100x150
	T5Z111100150R004	UT-3000 scale FHR 50 - 240 bpm	111x100x150
Hewlett-Packard	T5Z152100150RP01	M1350B scale FHR 50 - 210 bpm	152x100x150
	T5Z150100150VM00	M1350A / M1351A scale FHR 50 - 210 bpm	150x100x150
Huntleigh	T5Z210150150O000	Baby Dopplex BD 4000	210x150x150
	T5Z151150150O000	Baby Dopplex	151x150x150
Luckcome	T5Z111100150R001	L8 scale FHR 30 - 210 bpm	111x100x150

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Device name	Index number	Device model	Dimentions /
			A (mm) x B (m)
			/ x C (z-fold)
Aspel	T5R05015E16RM000	Ascard 1,	50x15
	T5R21020E17R0000	Ascard 612 / Mr Gold,	210x20
	T5R21025E17R0000	Ascard 612 / Mr Gold,	210x25
	T5R21040E17R0000	Ascard 612 / Mr Gold,	210x40
	T5R10440E17R0000	Ascard- 3,	104x40
	T5R06010E12R0000	Ascard- 31,	60x10
	T5R11010E12R0000	Ascard- 33,	110x10
	T5R11014E12R0000	Ascard- 33,	110x14
	14 P.d. T5R11225E12R0000	Ascard- A4/B56/Mr Blue/Mr Silver/Mr Grey,	112x25
	T5R05825E12R0000	Ascard- B1/ Mr Green / B5 Eco,	58x25
	T5R06025E12R0000	Ascard- B5, Mr Red,	60x25
	T5Z210140300RM00	Ascard Gold	210x140x300
BTL	T5R21025E17R0000	08LC/ 08LT,	210x25
	T5R11225E12R0000	08MT/ 08MD/ 08MD3,	112x25
	T5R05825E12R0000	08SD1/ 08SD3/ 08SD6,	58x25
	T5Z210140300VM00	08LC / 08LT	210x140x300
Cardioline	T5Z112100300RM00	Delta 3 Plus	112x100x300
	T5R10020E12R0000	ECG 100L,	100x20
	T5Z100150180R000	ECG 100+	100x150x180
	T7Z210295180RM00	ECG 200+	210x295x180
Cardiorapid	T5R06015E16RM000	K-130B,	60x15
	T5R05015E16RM000	K-112,	50x15
	T5R13430E16RM000	K-131,	134x30
	T5R13025E16RM000	K-300P,	130x25
	T5Z050070200RM00	K-312D	50x70x260
	T5R12030E19RM000	K-33, K-36, Exel 103,	120x30
	T5R12020E16RM000	K-360B,	120x20
Comen	T5R08020E12R0000	CM300,	80x20

	T5Z110140145RM00	CM600	110x140x145
	T5R21525I16R0000	CM1200,	215x25
	T5R21530E16R0000	CM1200,	215x30
Edan	T5R08020E12R0000	SE-3,	80x20
	T5R08030E12R0000	SE-3,	80x30
	T5R21025E17R0000	SE-6/ SE-12 SE-12 express / SE-1200,	210x25
	T7Z210295150RM00	SE-6 / SE-12 SE-12 express / SE-1200	210x295x150
	T5Z110140145RM00	SE-601	110x140x145
	T5Z210140215RM00	SE-1201	210x140x215
Esaote Biomedica	T5R09028E19R0000	P 80,	90x28
	T5Z090070400RM00	P 80	90x70x400
	T5Z080070315RM00	P 8000	80x70x315
Farum	T5R12020E16RM000	Ar- 1200,	120x20
	T5R06015E15M0000	Ar- 600,	60x15
	T5R10040I15R0000	E-30,	100x40
	T5R05030I15R0000	E-10 ,	50x30
	T5R05030E15R0000	E-110,	50x30
	T5R20920E20RM000	Dedalus,	209x20
	T5R11040E17R0000	E-300/ E-330,	110x40
	T5R08020E12R0000	E-30G,	80x20
	T5R11034E17R0000	E- 600 / E- 60,	110x34
	T5R11020E17R0000	E-600/E300/E60,	110x20
	T5R05015E16RM000	MicroCard,	50x15
	T5R13025E16RM000	MidiCard / K-300P,	130x25
Fukuda	T5R11030E16R0000	Denshi OP30KE,	110x20
	T5R11030E16R0000	Denshi OP30KE,	110x30
	T5R06330I16R0000	OP110TE/ 119TE,	63x30
	T5R21030I16V0000	OP69TE / 353TE,	210x30
	T5R14430I16R0000	OP358TE,	144x30
	13 P.d. T5R14430E16R0000	FD31-FD34-35/36,	144x30
	T5Z110140145RM00	FX7202- OP222TE	110x140x145
	T5Z0631004000M00	ALPHA 1000, OP-219TE	63x100x400
Hellige	T7Z210295150RM00	Cardiosmart MAC 1200/1600	210x295x150
	T5R05540E16R0000	EK-41-EK-51,	55x40
	T5Z130135370RM00	EK-53-EK-56	130x135x370
	T7Z080090280RM00	Microsmart MAC 400/600	80x90x280
	T7Z090090360RM00	Microsmart MAC 500	90x90x360
	9 P.d. T7Z110140200RM00	Microsmart MAC 800	110x140x200

HP / Phillips	T7Z210300200RP00	HP/ Philips M1709A	210x300x200
	T7Z210300100RP00	HP/ Philips TRIM I/II/III	210x300x100
Innomed 19 P.d.	T5R11225E12R0000	Heart Scen 112 C-D,	112x25
	T5R05825E12R0000	Heart Scen 60G - Heart Mirror,	58x25
	T5R08020E12R0000	Heart Scen 80 G-L,	80x20
Marquette 21 P.d.	T7Z090090360RM00	MAC 500	90x90x360
	T7Z080090280RM00	MAC 400/600	80x90x280
	T7Z210280300RP00	Case 12/15/16 MAC 3000/5000	210x280x300
	T7Z210295150RM00	MAC 1200	210x295x150
	T5Z215280300RP00	MAC LAB 3000	215x280x300
Medea	T5R05714E12R0000	MedeaLine 3,	57x14
	T5R11214E12R0000	MedeaLine 6,	112x14
Medigate	T5R08020E12R0000	MeCA 303i,	80x20
	T5R11225E12R0000	MeCA 412i,	112x25
	T5Z216280200RM00	MeCA 812i	216x280x200
Mortara 15 P.d.	T5Z050070200RM00	Eli 50	50x70x200
	T5R10823E16R0000	Eli 100,	108x25
	T7Z108140200RM00	Eli 150	108x140x200
	T5Z216280250RM00	Eli 250	215x280x250
	T7Z210280250RM00	Eli 380	210x280x250
	T7Z210300200RM00	Eli Xscribe Z200	210x300x200
	T5R21020E19R0000	Eli 230,	210x20
Mindray	T5R08020E12R0000	BeneHeart R3,	80x20
	T5Z080070200RM00	BeneHeart R3	80x70x200
	T5Z210295150RM00	BeneHeart R12	210x295x150
Nihon Khoden 20 P.d.	T5Z110140143RM00	ECG-9010, ECG-9020, ECG-9022	110x140x143
	T5Z210140215RM00	ECG-9130 / ECG-9110	210x140x215
Schiller 7 P.d.	T5Z090090400VM00	AT-1	90x90x400
	T7Z210280215VM00	AT-2 Plus	210x280x215
	T5Z210280215VM00	AT-2	210x280x215
	T7Z210280143RM00	AT-102 Plus	210x280x143
	T5Z210280143RM00	AT-102	210x280x143
	T5Z080070315RM00	AT-101 - Defiguard 6002	80x70x315
	T5Z070100200RM00	AT-3	70x100x200
	T7Z090090250RM00	AT-4	90x90x250
	T5Z144100350VM00	AT-6	144x100x350
	T5Z210140250RM00	AT - 10	210x140x250
	T7Z210140156RM00	AT - 10 Plus	210x140x156
	T7Z210140156RM00	AT-110 Plus	210x140x156
	T5Z210140150RM00	AT-110	210x140x150

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Index number	Category	Dimentions
		/ A (mm) x B (m)
T5R03810E12O0000	Laboratory printer	38x10
T5R05030E15O0000	Laboratory printer	50x30
T5R05025E15O0000	Laboratory printer	50x25
T5R05020E15O0000	Laboratory printer	50x20
T5R05706E12O0000	Laboratory printer	57x6
T5R05710E12O0000	Laboratory printer	57x10
6p.d. T5R05720E12O0000	Laboratory printer	57x20
T5R05725E12O0000	Laboratory printer	57x25
T5R05730E12O0000	Laboratory printer	57x30
T5R06030E12O0000	Laboratory printer	60x30
T5R11007E12O0000	Laboratory printer	110x7
T5R11010E12O0000	Laboratory printer	110x10
T5R11020E12O0000	Laboratory printer	110x20
T5R11030E12O0000	Laboratory printer	110x30
T5R11220E12O0000	Laboratory printer	112x20

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<i>22-23 P.d.</i> <i>8 P.d.</i>	T5Z210140150RM00	AT-110	210x140x150
	T5Z210280350RM00	AT-60	210x280x350
	T5Z11415064RM00	FT-1	114x150x64
	T5Z114095200RM00	MS 2010	114x95x200
	T5Z210150400RM00	CS 6/12	210x150x400
Siemens <i>5 P.d.</i>	T5Z104100300AM00	Cardiostat 31 / 31S	104x100x300
	T7Z210300200RP00	Megacard-740	210x300x200
	T5R14825E19R0000	Sicard-440,	148x25
	T5Z148100300RM00	Sicard-460	148x100x300
	T5Z210300500RM00	Sicard-740	210x300x500
Sonoscape	T5Z110140145AM00	IE - 6	110x140x145
	T5Z210150200AM00	IE - 12	210x150x200
Welch Allyn	T5Z080070250RM00	1500	80x70x250
	T5Z210280200RM00	CP100/200	210x280x200
	T5Z114070250RM00	CP-50	114x70x250

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