

## DECLARATION OF EC CONFORMITY


WE:

<u>Name of Manufacturer:</u>	Przedsiębiorstwo Innowacyjno - Handlowe VARIA Ltd.
<u>Manufacturer Address</u>	POLAND, 60-473 Poznan, 10 Biecka str.
<u>SRN (Single Registration Number)</u>	
<u>Basic UDI-DI</u>	590307622TPAPERKGN
<u>Name of product:</u>	<b>Recorder Thermal Paper for ECG Devices</b>
<u>Product size:</u>	aa x bb (aa x bb x cc) it depends on dimension and format type - See Annex I
<u>Product list:</u>	See Annex II
<u>Risk Class:</u>	Class I
<u>Quality System:</u>	ISO 13485
<u>Conformity assessment route:</u>	P.I.H. VARIA Sp. z o.o. uses the following procedure for the CE-labeling of their products according the 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

  
Jacek Witaszek  
Vice-President

Poznan, 25-05-2021

Rev A25052021v1.0.0

## 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)
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
	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
<b>Edan</b>	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
<b>Esaote Biomedica</b>	T5R09028E19R0000	P 80,	90x28
	T5Z090070400RM00	P 80	90x70x400
	T5Z080070315RM00	P 8000	80x70x315
<b>Farum</b>	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
<b>Fukuda</b>	T5R11030E16R0000	Denshi OP30KE,	110x20
	T5R11030E16R0000	Denshi OP30KE,	110x30
	T5R06330I16R0000	OP110TE/ 119TE,	63x30
	T5R21030I16V0000	OP69TE / 353TE,	210x30
	T5R14430I16R0000	OP358TE,	144x30
	T5R14430E16R0000	FD31-FD34-35/36,	144x30
	T5Z110140145RM00	FX7202- OP222TE	110x140x145
	T5Z0631004000M00	ALPHA 1000, OP-219TE	63x100x400
<b>Hellige</b>	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
	T7Z110140200RM00	Microsmart MAC 800	110x140x200

<b>HP / Phillips</b>	T7Z210300200RP00	HP/ Philips M1709A	210x300x200
	T7Z210300100RP00	HP/ Philips TRIM I/II/III	210x300x100
<b>Innomed</b>	T5R11225E12R0000	Heart Scen 112 C-D,	112x25
	T5R05825E12R0000	Heart Scen 60G - Heart Mirror,	58x25
	T5R08020E12R0000	Heart Scen 80 G-L,	80x20
<b>Marquette</b>	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
<b>Medea</b>	T5R05714E12R0000	MedeaLine 3,	57x14
	T5R11214E12R0000	MedeaLine 6,	112x14
<b>Medigate</b>	T5R08020E12R0000	MeCA 303i,	80x20
	T5R11225E12R0000	MeCA 412i,	112x25
	T5Z216280200RM00	MeCA 812i	216x280x200
<b>Mortara</b>	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
<b>Mindray</b>	T5R08020E12R0000	BeneHeart R3,	80x20
	T5Z080070200RM00	BeneHeart R3	80x70x200
	T5Z210295150RM00	BeneHeart R12	210x295x150
<b>Nihon Khoden</b>	T5Z110140143RM00	ECG-9010, ECG-9020, ECG-9022	110x140x143
	T5Z210140215RM00	ECG-9130 / ECG-9110	210x140x215
<b>Schiller</b>	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

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

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