

### MANUFACTURER

SORIMEX spółka z ograniczoną odpowiedzialnością spółka komandytowa  
ul. Równinna 25, 87-100 Toruń, Poland

### WE DECLARE UNDER OUR SOLE RESPONSIBILITY THAT:

### MEDICAL DEVICE:

ECG electrodes

### MODELS:

EK-S, EK-1, EKK, EP

### CLASS:

I rule I according to Annex IX of 93/42/EEC Directive

- meets all provisions of Directive 93/42/EEC which apply to it.

Conformity assessment procedure:

- Annex VII of 93/42/EEC directive (chapter 5 and 6 of Annex VII are not applicable).

### APPLIED HARMONIZED STANDARDS, NATIONAL STANDARDS OR OTHER NORMATIVE DOCUMENTS:

- EN ISO 13485:2012 + EN ISO 13485:2012/AC:2012
- EN ISO 14971:2012
- EN 1041:2008
- EN ISO 15223-1:2012
- EN ISO 10993-1:2009

Batch numbers of the products covered by this declaration can be found on the Quality Control Certificate confirming the release of product for sale and should be treated as part of this declaration.



Mariusz Sobociński

Prezes Zarządu

### LIST OF TYPES OF CONSTRUCTION ECG ELECTRODES COVERED BY THE DECLARATION OF CONFORMITY

EK-S 25 P EK-S 25 PSG EK-S 25 PSG RTG	EK-S 30 P EK-S 30 PSG EK-S 30 PSG RTG EK-S 30 WpSG	EK-S 35 PSG ST	EK-S 40 P EK-S 40 PSG EK-S 40 PSG RTG	EK-S 42 P EK-S 42 PSG EK-S 42 PSG RTG
EK-S 44 P EK-S 44 PSG EK-S 44 PSG RTG	EK-S 45 P EK-S 45 PSG EK-S 45 PSG RTG	EK-S 50 P EK-S 50 PSG EK-S 50 PSG RTG EK-S 50 WpSG	EK-S 50 P/L EK-S 50 PSG/L EK-S 50 PSG/L RTG	EK-S 54 P EK-S 54 PSG EK-S 54 PSG RTG
EK-S 55 P EK-S 55 PSG EK-S 55 PSG RTG	EK-S 56 P EK-S 56 PSG EK-S 56 PSG RTG	EK-S 60 P EK-S 60 PSG EK-S 60 PSG RTG	EK-S 60 P XC EK-S 60 PSG XC	EK-S 61 P EK-S 61 PSG EK-S 61 PSG RTG
EK-1-2j/L-50 EK-1-2j/RTG/L-50 EK-1-3/L-18	EK-1/30 PHG/2j-L50 EK-1/30 PHG/2j-L50/RTG EK-1/23 WpHG/2j-L50 EK-1/23 WpHG/2j-L50/RTG	EKK-1 Ekk-2	EP-15 EP-24 EP-30	



Mariusz Sobociński

Prezes Zarządu

### MANUFACTURER

SORIMEX sp. z o.o. sp. k  
ul. Równinna 25, 87-100 Toruń, Polska

### WE DECLARE UNDER OUR SOLE RESPONSIBILITY THAT

### THE MEDICAL DEVICES

Disposable NIBP cuffs  
Reusable NIBP cuffs

### MODELS

**disposable NIBP cuffs type: MSJ, MDJ**  
**reusable NIBP cuffs type: MSWB, MSWZ, MDWB, MDWZ**  
for detailed specification see annex

### OF CLASS

I rule I according to Annex IX of 93/42/EEC directive

Meets all provisions of the directive 93/42/EEC which apply to it.  
Conformity assessment procedure: Annex VII of 93/42/EEC directive (chapter 5 and 6 of Annex VII is not applicable).

### APPLIED HARMONIZED STANDARDS, NATIONAL STANDARDS OR OTHER NORMATIVE DOCUMENTS

- EN ISO 13485:2003+AC:2009
- EN ISO 14971:2009
- EN 980:2008
- EN 1041:2008
- EN ISO 10993-1:2009
- EN ISO 10993-5:2009
- EN ISO 10993-10:2010
- EN 1060-1:1995+A2:2009
- EN 1060-2:1995+A1:2009
- EN 1060-3:1997+A2:2009

Batch numbers of products covered by this declaration can be found on the documentation of releasing of goods for sale: Form F1-4.10/3, to be considered as a part of this declaration.

Mariusz Sobociński

Chairperson Of The Board



List of constructional types covered by the declaration of conformity

Reusable NIBP cuffs

MSWZ-LA	MDWZ-LA	MSWB-LA	MDWB-LA
MSWZ-A	MDWZ-A	MSWB-A	MDWB-A
MSWZ-P	MDWZ-P	MSWB-P	MDWB-P
MSWZ-I	MDWZ-I	MSWB-I	MDWB-I
MSWZ-N	MDWZ-N	MSWB-N	MDWB-N
MSWZ-T	MDWZ-T	MSWB-T	MDWB-T
MSWZ-SA	MDWZ-SA	MSWB-SA	MDWB-SA
MSWZ-AL	MDWZ-AL	MSWB-AL	MDWB-AL
MSWZ-LAL	MDWZ-LAL	MSWB-LAL	MDWB-LAL

Dispsable NIBP cuffs

MSJ-01-U	MDJ-01-U	MSJ-01-W	MDJ-01-W
MSJ-02-U	MDJ-02-U	MSJ-02-W	MDJ-02-W
MSJ-03-U	MDJ-03-U	MSJ-03-W	MDJ-03-W
MSJ-04-U	MDJ-04-U	MSJ-04-W	MDJ-04-W
MSJ-05-U	MDJ-05-U	MSJ-05-W	MDJ-05-W
MSJ-LAL-U	MDJ-LAL-U	MSJ-LAL-W	MDJ-LAL-W
MSJ-LA-U	MDJ-LA-U	MSJ-LA-W	MDJ-LA-W
MSJ-AL.-U	MDJ-AL.-U	MSJ-AL.-W	MDJ-AL.-W
MSJ-A-U	MDJ-A-U	MSJ-A-W	MDJ-A-W
MSJ-SA-U	MDJ-SA-U	MSJ-SA-W	MDJ-SA-W
MSJ-P-U	MDJ-P-U	MSJ-P-W	MDJ-P-W
MSJ-I-U	MDJ-I-U	MSJ-I-W	MDJ-I-W
MSJ-T-U	MDJ-T-U	MSJ-T-W	MDJ-T-W

Mariusz Sobociński

Chairperson Of The Board

### Gamintojas

SORIMEX ul. R6wninna 25, 87-100 Torun, Poland

### Atsakingai patvirtiname, kad

### MEDICINOS PRIETAISAS:

EKG elektrodai

### MODELIAI:

EK-S, EK-1, EKK, EP

### KLASĖ 1:

pagal IX of 93/42/EEC Direktyvos IX priedo I taisyklę atitinka visus Direktyvos 93/42/EEC reikalavimus

Atitikties vertinimo procedūra pagal Direktyvos 93/42EEC

Priedą VII (5 ir 6 VII Priedo skyriai netaikomi)

### Atitinka šiuos suderintus standartus ir kitus normatyvinius dokumentus:

- EN ISO 13485:2012 + EN ISO 13485:2012/AC:2012
- EN ISO 14971 :2012
- EN 1041:2008
- EN ISO 15223-1 :2012
- EN ISO 10993-1:2009

MARIUSZ SOBOCHINSKI PARAŠAS