

DECLARATION OF CONFORMITY

According to ISO/IEC Guide 22 i PN-EN 45014

Manufacturer: Przedsiębiorstwo Produkcji i Handlu MEDRIV Spółka z O.O.

Address: 04-051 Warszawa ul. Poligonowa 2/18, Tel : 022 761 20 19

Classification: Reagents for blood gas analyzers and electrolytes analyzers

L.p.	Catalogue no.	Name	Description	Application
1	MV 10/11	Cal-Pack 248	pH calibrator	Coming 248
2	MV 012W	Wash 248	washing solution	Coming 248
3	MV 10/12	Cal-Pack 238	pH calibr./ washing sol.	Coming 238
4	MV D/C	Deprot./Condit.	Conditioning solution	Coming 248/ 614/ 644
5	MV 10B1	Bufor 1	pH calibrator	AVL Compact 2
6	MV 11B2	Bufor 2	pH calibrator	AVL Compact 2
7	MV 012RA	Płyn Pt. Koncentrat	washing solution	AVL Compact 2
8	MV 013CSA	Płyn Czyszczący A	maintanance solution	AVL C-2, AVL ISE
9	MV 013CSB	Płyn Czyszczący B	maintanance solution	AVL C-2, AVL ISE
10	MV 014REF	pH Reference	ereference solution	AVL Compact 2
11	MV 020AC	Acidbasal acidosis	BG and electrolytes control	Coming (BG,FF), AVL (BG)
12	MV 020NO	Acidbasal normal	BG and electrolytes control	Coming (BG,FF), AVL (BG)
13	MV 020AL	Acidbasal alkalosis	BG and electrolytes control	Coming (BG,FF), AVL (BG)
14	MV 01Na/K	Kalibr. Na-140 K-5	Na, K calibrator	Coming 480
15	MV 02Na/K	Kalibr. Na-160 K-80	Na, K calibrator	Coming 480
16	MV 053Li	Stand. Wew. 3 mol Li	reference solution	Coming 480
17	MV 07 HCl/P	Płyn odb. n/b Pep.	Maintanace solution	Coming 480
18	MV 01Na/K/Ca	Standard A/Ca	Na, K, Ca, pH calibrator	AVL ISE
19	MV 01Na/K/Cl	Standard A/Cl	Na, K, Cl calibrator	AVL ISE
20	MV 02Na/K/Ca	Standard B/Ca	Na, K, Ca, pH calibrator	AVL ISE
21	MV 02Na/K/Cl	Standard B/Cl	Na, K, Cl calibrator	AVL ISE
22	MV 02Na/K/Cl/III	Standard B/III	Na, K, Cl calibrator	AVL ISE
23	MV 03Na/K/Li	Standard C	Li calibrator	AVL ISE
24	MV 014ISE/REF	ISE-Reference	reference solution	AVL ISE
25	MV 1214Cl	Cal-Pack 9130	Na, K, Cl calibrator	AVL ISE
26	MV 1214Ca	Cal-Pack 9140	Na, K, Ca calibrator	AVL ISE
27	MV 015Na	Kondycjoner El. Na	maintanace solution	AVL ISE
28	MV 021/I	ISE Control level I	Na, K, Ca, Cl, Li control	AVL (ISE) / Coming (ISE)
29	MV 021/II	ISE Control level II	Na, K, Ca, Cl, Li control	AVL (ISE) / Coming (ISE)
30	MV 021/III	ISE Control level III	Na, K, Ca, Cl, Li control	AVL (ISE) / Coming (ISE)
31	MV 0102Na/K	Cal-Pack 614	Na, K calibrator	Coming 614
32	MV 0102Na/K/Cl	Cal-Pack 644	Na, K, Cl calibrator	Coming 644
33	MV 0102E/L	Cal-Pack E/L Plus	Na, K, Cl, Li calibrator	Medica Easy Lyte / Plus

Hereby on self responsible we declare, that the *In vitro* diagnostics products mentioned above, fulfill basic requirements according to Health Minister regulation of "Basic Requirements for *In vitro* Diagnostics Products Appendix 1".

Documents prepared according to Health Minister regulation of "Basic Requirements for *In vitro* Diagnostics Products Appendix 3". Documents are to insight in manufacturer headquarters up to five years after production finish.

Norms appliction: ISO 13485/2002, ISO 9000/2001

Additional information: products mentioned above are CE marked.

Warszawa, 30.03.2018

Przedsiębiorstwo Produkcji i Handlu

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