Declaration of Conformity

Diamond PROLYTE, Medica EasyLyte, IL ILyte, Menarini SpotLyte Accessories

Manufacturer	European Union Representative
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Product Information

Calibrators		
ME-2121D Fluid Pack Na/K – Na/K/Cl – Na/K/Cl/Li – Na/K/Li	IL-2121D Fluid Pack Na/K – Na/K/Cl – Na/K/Cl/Li – Na/K/Li	MN-2121D Fluid Pack Na/K/Cl/Li ME-2123D Fluid Pack Na/K/Ca/pH IL-2123D Fluid Pack Na/K/Ca/pH
Support (Accessory) Reagents		
ME-2111D Urine Diluent ME-2118D Daily Rinse Kit	ME-2309D Flush Solution ME-2492D Internal Filling Solution	ME-2577D Urine Standard ME-2578D Red Test Dye
Quality Controls		
DD-92001 Level 1 DD-92002 Level 2	DD-92003 Level 3 DD-92004 Level 4	DD-92123 Tri Level DD-92900 Mission Complete Linearity Controls, 5 Levels
Instrument Accessories		
ME-2102D Na^+ Electrode ME-2101D K^+ Electrode ME-2113D Cl^- Electrode ME-2150D Ca^{++} Electrode ME-2103D Reference Electrode	ME-2257D Sample Detector ME-2258D Membrane Assembly ME-2104D Pump Tubing ME-2100D Calcium Tubing Kit ME-2541D Printer Paper	ME-2107D Sample Probe ME-2108D Solutions Valve ME-2323D Probe Wiper ME-2095D Maintenance Kit ME-2572D Troubleshooting Service Kit

Regulatory Information

The product herewith complies with the requirements of the *in vitro* Diagnostic Medical Device Directive 98/79/EC and carries the CE marking accordingly.

Agent: _____

Hubert Kulzer, Managing Director, Diamond Diagnostics GmbH

Date: 23 November, 2009 München, Germany

Controlled

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