

Certificate

Herewith we, OMRON HEALTHCARE Co., Ltd. certify HEM-6121 (HEM-6121-AP) is substantially equivalent to RS3 (HEM-6130-E)* which is clinically validated and employs the same algorithm as the predicate device for determining blood pressure.

Very Truly Yours,

*Hakuo Takahashi, Masamichi Yoshika and Toyohiko Yokoi. Validation of Omron RS8, RS6, and RS3 home blood pressure monitoring devices, in accordance with the European Society of Hypertension International Protocol revision 2010. *Vascular Health and Risk Management* 2013:9 265–272.

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