

Certificate

Herewith we, OMRON HEALTHCARE Co., Ltd. certify HEM- 6181 (HEM- 6181-AP) is substantially equivalent to HEM-6181* which is clinically validated and employs the same algorithm as the predicate device for determining blood pressure.

Very Truly Yours,

*Kanako Harada, Yukiko Hishiki and Hakuo Takahashi. Validation of two automatic devices, Omron HEM-6232T and HEM-6181, for self-measurement of blood pressure at the wrist according to the ANSI/AAMI/ISO 81060-2:2013 protocols and the European Society of Hypertension International. *Vascular Health and Risk Management* 2019:15 1–9.

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