



Certificate

Herewith we, OMRON HEALTHCARE Co., Ltd. certify HEM- 6161 (HEM- 6161-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.

March, 11, 2019

A handwritten signature in blue ink, reading "Kazunobu Itonaga", is written over a horizontal line.

Kazunobu Itonaga

General Manager

Product Development Department

Product Development Strategy HQ