



Certificate

Herewith we, OMRON HEALTHCARE Co., Ltd. certify HEM-6221 (HEM-6221-AP) is substantially equivalent to RS6 (HEM-6221-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.

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