

Certificate

Herewith we, OMRON HEALTHCARE Co., Ltd. certify the blood pressure monitor HEM-7121J (HEM-7121J-IN) is substantially equivalent to HEM-7130 (Japanese model)* with HEM-CR24 cuff which is clinically validated employs the same algorithm as the predicate device for determining blood pressure.

*Hakuo Takahashi, Masamichi Yoshika and Toyohiko Yokoi. Validation of three automatic devices for the self-measurement of blood pressure according to the European Society of Hypertension International Protocol revision 2010: the Omron HEM-7130, HEM-7320F, and HEM-7500F. *Blood Pressure Monitoring* 2015, 20:92–97.

Very Truly Yours,

February 24, 2021

Kazunobu Itonaga

Senior General Manager

Product Development HQ