

Certificate

Herewith we, OMRON HEALTHCARE Co., Ltd. certify the blood pressure monitor HEM-7140T1-AP, HEM-7141T1-AP, HEM-7142T1-AP, HEM-7143T1-AP are substantially equivalent to HEM-9200T (Japanese model)* with HEM-RML31 cuff which is clinically validated employs the same algorithm and the same components as the predicate device for determining blood pressure.

*Hakuo Takahashi, Kanako Saito and Nobuki Yakura. Validation of Omron HEM-9200T, a home blood pressure monitoring device for the upper arm, according to the American National Standards Institute/Association for the Advancement of Medical Instrumentation/International Organization for Standardization 81060-2:2013 protocol. Journal of Human Hypertension 09 April 2021

Very Truly Yours,

APR 19, 2022

Takanori Nishioka

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