

Certificate

Herewith we, OMRON HEALTHCARE Co., Ltd. certify the blood pressure monitor HEM-7127-JE3 is substantially equivalent to HEM-9200T * with HEM-CR24 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,

Nov. 18, 2024

Shinichi Ito

Cardiovascular Product Development Department

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General Manager