



Certificate

Herewith we, OMRON HEALTHCARE Co., Ltd. certify the blood pressure monitors below are substantially equivalent to HEM-9200T* which is clinically validated in following clinical study and employs the same algorithm and the same components as the predicate device for determining blood pressure.

- EZ BT Large (HEM-7183T1-LAP)
- EZ Large (HEM-7183-LAP)

*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

Note: The validation study for HEM-9200T is carried out with 3 cuffs, including HEM-RML31 (22-42cm). According to the sales strategy, HEM-RML31 is bundled with the main units listed above.

Very Truly Yours,

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