



# Certificate

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

Current monitors	Validated predicate monitor	Clinical paper info.
HEM-7211 <i>Standard cuff: HEM-CR24</i>	HEM-9200T	*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; HEM-CS24(17-22cm), HEM-CR24(22-32cm), and HEM-RML31(22-42cm). According to the sales strategy, either CR24 or RML31 is bundled with the main unit and either an assortment of CS24/CR24/RML31 or CS24/RML31 or CR24/RML31 is set as optional accessory.

Very Truly Yours,

Dec. 21, 2024

Takehiro Hamaguchi  
Product Development HQ  
General Manager