



## Certificate

Herewith we, OMRON HEALTHCARE Co., Ltd. certify the blood pressure monitors below are substantially equivalent to HEM-7130\*<sup>1</sup> and HEM-9200T\*<sup>2</sup> which are 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 Power (HEM-7183T1-CAP)
- EZ BT (HEM-7183T1-AP)
- EZ Power (HEM-7183-CAP)
- EZ (HEM-7183-AP)
- EZ Lite (HEM-7180-AP)
- EZ Super Lite (HEM-7090-AP)

\*<sup>1</sup> Hakuo Takahashi, Masamichi Yoshika, 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

\*<sup>2</sup> 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 studies for HEM-7130 and HEM-9200T are carried out with 3 cuffs, including HEM-CR24 (22-32cm). According to the sales strategy, HEM-CR24 is bundled with the main units listed above.

Very Truly Yours,

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