



Certificate

Herewith we, OMRON HEALTHCARE Co., Ltd. certify the blood pressure monitor Complete(HEM-7530T-AP3) is 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,

Feb 13, 2024

Takanori Nishioka
Cardiovascular Product Development Department
General Manager



Certificate

Herewith we, OMRON HEALTHCARE Co., Ltd. certify HEM-9200T is substantially equivalent to HEM-7130 (Japanese model) and M6 AC (HEM-7322-E), both clinically validated. It employs the same algorithm and the same components as the predicate device for determining blood pressure. HEM-7130 (Japanese model) and M6 AC (HEM-7322-E) fulfill requirements of International Protocol revision 2010 by European Society of Hypertension.*¹

[Reference]

1. Dabl Educational Trust. Blood pressure monitors-validation, papers, and reviews. Available at: <http://www.dableducational.org>. [Accessed 29 March 2016].

Very Truly Yours,

April 1, 2016

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