

Certificate

Herewith we, OMRON HEALTHCARE Co., Ltd. certify the blood pressure monitor HEM-7156(HEM-7156-AP),HEM-7156-A(HEM-7156-AAP), HEM-7156T (HEM-7156T-AP), HEM-7156T-A (HEM-7156T-AAP), HEM-7155T (HEM-7155T-AP), HEM-7361T (HEM-7361T-AP), HEM-7600T (HEM-7600T-AP3) are substantially equivalent to HEM-7134-E (M3 Comfort) * 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.

* Jirar Topouchian, Zoya Hakobyan, Jennifer Asmar, Svetlana Gurgenian, Parounak Zelveian Roland Asmar. Clinical accuracy of the Omron M3 Comfort® and the Omron Evolv® for self-blood pressure measurements in pregnancy and pre-eclampsia – validation according to the Universal Standard Protocol.

Vascular Health and Risk Management Volume 2018:14 Pages 189—197

Very Truly Yours,

Jan 16, 2024

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