



## Certificate

Herewith we, OMRON HEALTHCARE Co., Ltd. certify the blood pressure monitor HEM-7383T1-AP is substantially equivalent to HEM-7134-E (M3 Comfort) \* which is clinically validated employs the same algorithm and the same components as the predicate device for determining blood pressure. (This validation applies only to blood pressure measurement accuracy.)

\* Jirar Topouchian, Zoya Hakobyan , Jennifer Asmar , Svetlana Gurgonian , 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,

January 26, 2026

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