OMRON

Certificate

Herewith we, OMRON HEALTHCARE Co., Ltd. certify the blood pressure monitors below are substantially equivalent to M3 Comfort (HEM-7134-E)*1 and BP760N (HEM-7320-Z)*2 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. (This validation applies only to blood pressure measurement accuracy.)

- HEM-7383T1 (HEM-7383T1-AP)
- IQ BT Power (HEM-7194T1-FLCAP)
- IQ BT (HEM-7194T1-FLAP)
- IQ Power (HEM-7193-FLCAP)
- IQ (HEM-7193-FLAP)

*1 Hakuo Takahashi. Validation of Home Blood Pressure-monitoring Devices Omron EVOLV (HEM-7600T-E), HEM-9210T, and M3 Comfort (HEM-7134-E) According to European Society of Hypertension International Protocol (ESH-IP) Revision 2010. J. Clin. Physiol., Vol.49, No. 1, 2019.

*2 Takahashi H, Yoshika M, Yokoi. Validation of two automatic devices for the self-measurement of blood pressure according to the ANSI/AAMI/ISO81060-2:2009 guidelines: the Omron BP765 (HEM-7311-ZSA) and the Omron BP760N (HEM-7320-Z).
Vascular Health and Risk Management 2015 Jan 9;11:49-53

Very Truly Yours,

March 05, 2026

Shinichi Ito

Shinichi Ito
Cardiovascular Product Development Department
General Manager

OMRON HEALTHCARE Co., Ltd
53,Kunotsubo,Terado-cho,Muko,KYOTO,617-0002 JAPAN