



## Certificate

Herewith we, OMRON HEALTHCARE Co., Ltd. certify the blood pressure monitors below are substantially equivalent to FDA approved model BP760N (HEM-7320-Z) and European CE-marked model M3 Comfort (HEM-7134-E) which are clinically validated and employ the same algorithm and use components (sensor, pump, inflation/deflation control and cuff) as the predicate device for determining blood pressure.

- M7 Intelli IT (HEM-7361T-EBK)
- X7 Smart (HEM-7361T-ESL)
- M500 Intelli IT (HEM-7361T-D)
- M7 Intelli IT (HEM-7361T-ALRU)
- M6 Comfort (HEM-7360-E)
- X6 Comfort (HEM-7360-EO)
- M400 Intelli IT (HEM-7155T-D)
- M4 Intelli IT (HEM-7155T-EBK)
- X4 Smart (HEM-7155T-ESL)
- M3 Comfort (HEM-7155-E)
- X3 Comfort (HEM-7155-EO)
- M400 Comfort (HEM-7155-D)
- M4 Intelli IT (HEM-7155T-ALRU)
- M3 Comfort (HEM-7155-ALRU)

Very Truly Yours,

June, 10, 2019

Kazunobu Itonaga  
General Manager  
Product Development Department  
Product Development Strategy HQ



## Certificate

Herewith we, OMRON HEALTHCARE Co., Ltd. certify the blood pressure monitors below are substantially equivalent to BP760N (HEM-7320-Z)\*1 / HEM-7320-LA \*2 which are clinically validated and employ the same algorithm as the predicate device for determining blood pressure.

- HEM-7346T-AP3(JPN710T)
- HEM-7158T-AP3(JPN610T)
- HEM-7159T-AP3(JPN616T)
- HEM-7156-AP
- HEM-7156T-AP
- HEM-7155T-AP

Very Truly Yours,

\*1 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

\*2 Grover-Páez F1, Cardona-Muñoz EG, Cardona-Müller D, Guzmán-Saldívar VH, Rodríguez-De la Cerda M, Jiménez-Cázarez MB, Totsuka-Sutto SE, Alanis-Sánchez GA, Ramos-Becerra CG. Validation of the Omron HEM-7320-LA, upper arm blood pressure monitor with Intelli Wrap Technology Cuff HEM-FL1 for self-measurement and clinic use according to the European Society of Hypertension International Protocol revision 2010 in the Mexican population.

*Blood Pressure monitoring* 2017 Dec;22(6):375-378

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Kazunobu Itonaga

Product Development HQ

Senior General Manager