



Certificate

Herewith we, OMRON HEALTHCARE Co., Ltd. certify HEM-7156 (HEM-7156AP) and HEM-7361T (HEM-7361T-AP) 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.

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

October, 8, 2019

Kazunobu Itonaga

General Manager

Product Development Department

Product Development Strategy HQ