



OMRON HEALTHCARE Co., Ltd.

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PDS-BD1-15-0029

Certificate

Here with we, OMRON HEALTHCARE Co., Ltd. certify blood pressure monitors below are substantially equivalent to M6 AC (HEM-7322-E) and HEM-7130 (Japanese model), both clinically validated. They employ the same algorithm and the same components as the predicate device for determining blood pressure.

HEM-7121 (HEM-7121-AU)

HEM-7130 (HEM-7130-AU)

HEM-7322 (HEM-7322-AU)

HEM-7120 (HEM-7120-AP)

HEM-7121 (HEM-7121-AP)

HEM-7130 (HEM-7130-AP)

HEM-7130-L (HEM-7130-LAP)

HEM-7322 (HEM-7322-AP)

Very Truly Yours,

October 8, 2015

Manabu Hamamoto

General Manager

Bio-Information System Development Department1