

OMRON

OMRON HEALTHCARE Co., Ltd.

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HDV-BP-092122

Certificate

Herewith we, OMRON HEALTHCARE Co., Ltd, certify that the blood pressure monitor HEM-4030 series are substantially equivalent to HEM-4011C series and employs the same algorithm and the same components as the predicate device for determining blood pressure.

Very Truly Yours,

October 9, 2009

Takahide Tanaka

Takahide Tanaka

General Manager

Product Strategy HQ, Bio-Information System

Development Department