

Declaration

Herewith we, OMRON HEALTHCARE Co., Ltd., declare that the blood pressure monitors model JPN601, JPN700, JPN800 are substantially equivalent to blood pressure monitor HEM-7221-HK, registered to Korea FDA (Registration No. 12-158), which is clinically validated and employs the same hardware module and algorithm to perform the complete measurements of blood pressure. And it is also the same as our product HEM-773-Z used in Clinical evaluation report described below.

Therefore, Clinical evaluation report (Report number: MCS-CN-02015) tested according to the British Hypertension Society (BHS) and Association for the Advancement of Medical Instrumentation (AAMI) protocol is also applicable to the following blood pressure monitors.

Product

OMRON Automatic Blood Pressure Monitor

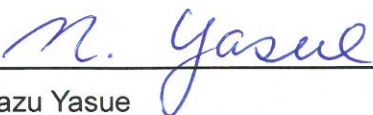
Model:

JPN601

JPN700

JPN800

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OMRON HEALTHCARE Co., Ltd.