(Form No.8-4)

**MINISTRY OF HEALTH, LABOUR AND WELFARE**

**GOVERNMENT OF JAPAN**

**2-2, KASUMIGASEKI 1-CHOME, CHIYODA-KU, TOKYO 100-8916**

**CERTIFICATE**

 It is hereby certified that the following in vitro diagnostic(s) marketed by (Name of the Marketing Approval Holder), (Address) is(are) manufactured(imported) under our supervision as stipulated in the Pharmaceuticals, Medical devices and Other Therapeutic Products Act of Japan and is(are) allowed to be sold in Japan.

Product(s) :

Date of Marketing Approval(Notification):

Marketing Approval(Notification) Number:

Reactive Ingredient(s):

Assay Procedure:

Intended Use:

No.

TOKYO, date

（医療機器審査管理課長名）

Director, Medical Device Evaluation Division

Pharmaceutical Safety Bureau

Ministry of Health, Labour and Welfare