



DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION DECLARATION FOR PRODUCTS SUBJECT TO RADIATION CONTROL STANDARDS	Form Approved OMB No. 57-R0120 <p style="text-align: center;">INSTRUCTIONS</p> 1. Type or print with ball point pen. <i>(One form per model #)</i> 2. Complete one copy for U.S. Customs Commerce 3. Attach all completed copies to the Canada Customs Invoice
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DISTRICT / PORT DIRECTOR OF CUSTOMS

PORT OF ENTRY	ENTRY NO.	DATE
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PRODUCT IDENTIFICATION

NAME AND ADDRESS OF MANUFACTURER:

NAME AND ADDRESS OF IMPORTER OF RECORD:

ULTIMATE CONSIGNEE *(If not Importer of Record)*

QUANTITY	TYPE	BRAND NAME	MODEL NO.
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FOR X - RAY, LIST APPROPRIATE SYSTEMS OR COMPONENT CATEGORY

AFFIRMATION *(Check appropriate statement and sign)*

I/WE hereby declare:

A. That the electronic products identified above were manufactured prior to the date of any applicable electronic product performance standard.

Date of Manufacture: _____

B. That the electronic products identified above comply with the performance Standards prescribed in Food and Drug Administration Rules 21 CFR 1010 which are applicable at date of manufacture and that a certificate in the form of a tag or label to this effect is affixed to each product.

C. That the electronic products identified above do not comply with the performance standards prescribed in Food and Drug Administration Rules 21 CFR 1010 but are being imported for the purpose of research, investigations, studies, demonstrations or training. An exception for these products has been or will be requested of the Director of the FDA Bureau of Radiological Health in accord with Section 360B (b) (42 U.S.C. 263j) of the Radiation Control for Health and Safety Act. They will not be introduced into commerce, and when their mission is completed they will be destroyed or exported under United States Customs Service supervision.

D. That the electronic products identified above do not comply with the performance standards prescribed in Food and Drug Administration Rules 21 CFR 1010 but that a timely and adequate petition for permission to bring the product into compliance with the applicable standard has been or will be filed with the Food and Drug Administration in accordance with 21 CFR 100.21. These products will remain under bond and not be introduced into commerce until notification is received from the Food and Drug Administration, that the products are in compliance with applicable standards.

Signature of Importer of Record _____

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DISTRICT / PORT DIRECTOR OF CUSTOMS

PORT OF ENTRY <i>For Customs Use Only</i>	ENTRY NO. <i>For Customs Use Only</i>	DATE <i>For Customs Use Only</i>
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PRODUCT IDENTIFICATION

NAME AND ADDRESS OF MANUFACTURER:

**MATSUI
JAPAN**

NAME AND ADDRESS OF IMPORTER OF RECORD:

**ABC COMPANY
123 Main Street
New York, New York 10001**

ULTIMATE CONSIGNEE *(If not Importer of Record)*

QUANTITY 1	TYPE COLOUR MONITOR	BRAND NAME PANASONIC	MODEL NO. EI-1611
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FOR X - RAY, LIST APPROPRIATE SYSTEMS OR COMPONENT CATEGORY

COMPLETE ONLY WHEN SHIPPING X -RAY EQUIPMENT

AFFIRMATION *(Check appropriate statement and sign)*

I/WE hereby declare:

A. That the electronic products identified above were manufactured prior to the date of any applicable electronic product performance standard.

Date of Manufacture: _____

B. That the electronic products identified above comply with the performance Standards prescribed in Food and Drug Administration Rules 21 CFR 1010 which are applicable at date of manufacture and that a certificate in the form of a tag or label to this effect is affixed to each product.

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Signature of Importer of Record Robert Smith