DECLARATION FOR IMPORTED ELECTRONICS PRODUCTS SUBJECT TO RADIATION CONTROL STANDARDS
の記入について

記入事項、項目にはおよそ下記の内容が書かれていますので、ご参考にしてください。

下記の①～⑦の必要事項を記入する

① 製造会社名、住所、原産国

② 輸入者名及び住所（荷受人様と輸入者が異なる場合は荷受人様も記入）

③ 内容品

④ 数量（型番ごと）

⑤ 型番とブランド名

⑥ 輸入者の署名（輸出者が添付する場合は、輸出者の署名）

⑦ 署名者の名前と肩書き（タイトル）

下記のA～Dから1つを選択し、その中の該当項目をさらに選択または記入する

□ A. FDA基準に従属しない（理由を下記1～7より選択） *インボイスの内容と一致していることが求められます

1. FDA基準設定以前の製造： 製造日
2. FDA基準又は指導の条項や定義適用から除外される： 除外の特別理由
3. アメリカに入国する個人の家庭用品又はアメリカ在住の方への返送
   （各製品に対して3品目のみ）
4. アメリカ国外在住の方の所有物で修理又は利用後、持ち主に返送する
5. 製造に使われる部品又は代替部品である
6. 輸入会社により製品開発される目的であり、" FOR TEST/EVALUATION ONLY "の
   ラベルが貼られ、輸出、廃棄又は後日のテストのため、保持される
7. P.L. 104-134又はFDAの指導に従って、再加工され、" FOR EXPORT ONLY " の
   ラベルが貼られ、FDAの許可なしに販売、配布、転送されない

□ B. FDA基準に合致している（合致理由を示す内容1～2から選択）、品物にFDA基準に合致したことを示すラベル、タグ（製造日が入った）がついていること

1. ラスト アニュアル リポート又はプロダクト/イニシャル リポート：
   リポートナンバーと製造業者名を記入
2. 製造業者やリポートナンバーが不明： 理由を記入

□ C. FDA基準に合致しない（合致しない状況説明を1～2から選択）、保税対象品、市販されていない、Radiation Protection Planのもとに使用する、下記の1、2の完了後、米国税関の監視のもと、輸出あるいは破棄

1. 研究、調査、トレーニング
2. トレードショウ、デモンストレーション： 日付と使用制限条件を記入する

D. FDA基準に合致しない（FDAからの許可を取得、申請中、申請予定状況説明を1～3から選択）、保税の状態、FDAからの許可・認可を取得するまで市販されない

1. 許可済み請願書の添付
2. 請願書の添付
3. リクエストが60日以内に提出される

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

DECLARATION FOR IMPORTED ELECTRONIC PRODUCTS SUBJECT TO RADIATION CONTROL STANDARDS

Form Approved OMB No. 0910-0025
Expiration Date: 11/30/2003

INSTRUCTIONS
1. If submitting entries electronically through ACS/ABI, hold FDA-2877 in entry file. Do not submit to FDA unless requested.
2. If submitting paper entry documents, submit the following to FDA:
   a. 2 copies of Customs Entry Form (e.g. CF 3461, CF 3461 Alt, CF 7501, etc.)
   b. 1 copy of FDA 2877
   c. Commercial Invoice(s) in English.

U.S. CUSTOMS PORT OF ENTRY ← ご 記 入 の 必 要	ENTRY NUMBER は ご ざ い ま	DATE OF ENTRY せ ん →

NAME & ADDRESS OF MANUFACTURING SITE; COUNTRY OF ORIGIN	NAME & ADDRESS OF IMPORTER & ULTIMATE CONSIGNEE *(if not importer)*
① ABC MACHINE JAPAN 1-2-3 HONCHO CHIYODA-KU TOKYO JAPAN COUNTRY OF ORIGIN: JAPAN	② ABC USA 111 NEW YORK, NY 1234 USA

PRODUCT DESCRIPTION	QUANTITY *(Items/Containers)*	MODEL NUMBER(S) & BRAND NAME(S)
③ DVD Player	④ 2 PIECES	⑤ FSCC1234 / MOONTECH

DECLARATION: I / WE DECLARE THAT THE PRODUCTS IDENTIFIED ABOVE: ***(Mark X applicable statements, fill in blanks, & sign)***

☐ **A. ARE NOT SUBJECT TO RADIATION PERFORMANCE STANDARDS BECAUSE THEY:**

- ☐ 1. Were manufactured prior to the effective date of any applicable standard; Date of Manufacture _____ .
- ☐ 2. Are excluded by the applicability clause or definition in the standard or by FDA written guidance.
  Specify reason for exclusion _____.
- ☐ 3. Are personal household goods of an individual entering the U.S. or being returned to a U.S. resident. (Limit: 3 of each product type).
- ☐ 4. Are property of a party residing outside the U.S. and will be returned to the owner after repair or servicing.
- ☐ 5. Are components or subassemblies to be used in manufacturing or as replacement parts (NOT APPLICABLE to diagnostic x-ray parts).
- ☐ 6. Are prototypes intended for on going product development by the importing firm, are labeled "FOR TEST/EVALUATION ONLY," and will be exported, destroyed, or held for future testing (i.e., not distributed). (Quantities Limited - see reverse.)
- ☐ 7. Are being reprocessed in accordance with P.L. 104-134 or other FDA guidance, are labeled "FOR EXPORT ONLY," and will not be sold, distributed, or transferred without FDA approval.

☒ **B. COMPLY WITH THE PERFORMANCE STANDARDS** WHICH ARE APPLICABLE AT DATE OF MANUFACTURE AND THAT A CERTIFICATION LABEL OR TAG TO THIS EFFECT IS AFFIXED TO EACH PRODUCT. COMPLIANCE DOCUMENTED IN:

- ☒ 1. Last annual report or Product/Initial report
  112233(Catalogue number) – _____ (ACCESSION NUMBER of Report)
  ABC MACHINE JAPAN (Name of MANUFACTURER OF RECORD *(Filed report with FDA/CDRH)*)
- ☐ 2. Unknown manufacturer or report number; State reason: _____

☐ **C. DO NOT COMPLY WITH PERFORMANCE STANDARDS;** ARE BEING HELD UNDER A TEMPORARY IMPORT BOND; WILL NOT BE INTRODUCED INTO COMMERCE; WILL BE USED UNDER A RADIATION PROTECTION PLAN; AND WILL BE DESTROYED OR EXPORTED UNDER U.S. CUSTOMS SUPERVISION WHEN THE FOLLOWING MISSION IS COMPLETE:

- ☐ 1. Research, Investigations/Studies, or Training (attach Form FDA 766)
- ☐ 2. Trade Show/Demonstration; List dates & use restrictions _____

☐ **D. DO NOT COMPLY WITH PERFORMANCE STANDARDS;** ARE HELD AND WILL REMAIN UNDER BOND; AND WILL NOT BE INTRODUCED INTO COMMERCE UNTIL NOTIFICATION IS RECEIVED FROM FDA THAT PRODUCTS HAVE BEEN BROUGHT INTO COMPLIANCE IN ACCORDANCE WITH AN FDA APPROVED PETITION. *(See Form FDA 766.)*

☐ 1. Approved Petition is attached. ☐ 2. Petition Request is attached. ☐ 3. Request will be submitted within 60 days.

WARNING: Any person who knowingly makes a false declaration may be fined not more than $10,000 or imprisoned not more than 5 years or both, pursuant to Title 18 U.S.C. 1001. Any person importing a non- compliant electronic product may also be subject to civil penalties of $1000 per violation, up to a maximum $300,000 for related violations pursuant to Title 21 U.S.C. 360pp.

SIGNATURE OF IMPORTER OF RECORD
⑥ 

NAME AND TITLE OF RESPONSIBLE PERSON
⑦ TARO YAMADA SALES

Public reporting burden for this collection of information is estimated to average 0.2 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Food and Drug Administration
CDRH (HFZ-342)
2094 Gaither Road
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DECLARATION FOR IMPORTED ELECTRONIC PRODUCTS SUBJECT TO RADIATION CONTROL STANDARDS

Form Approved OMB No. 0910-0025
Expiration Date: October 31, 2013

INSTRUCTIONS

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2. If submitting paper entry documents, submit the following to FDA:
   a. 2 copies of Customs Entry Form (e.g. CF 3461, CF 3461 Alt, CF 7501, etc.)
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   c. Commercial Invoice(s) in English.

U.S. CUSTOMS PORT OF ENTRY	ENTRY NUMBER	DATE OF ENTRY

NAME & ADDRESS OF MANUFACTURING SITE; COUNTRY OF ORIGIN	NAME & ADDRESS OF IMPORTER & ULTIMATE CONSIGNEE *(if not importer)*

PRODUCT DESCRIPTION	QUANTITY *(Items/Containers)*	MODEL NUMBER(S) & BRAND NAME(S)

DECLARATION: I / WE DECLARE THAT THE PRODUCTS IDENTIFIED ABOVE: ***(Mark X applicable statements, fill in blanks, & sign)***

☐ **A. ARE NOT SUBJECT TO RADIATION PERFORMANCE STANDARDS BECAUSE THEY:**

- ☐ 1. Were manufactured prior to the effective date of any applicable standard; Date of Manufacture _____ .
- ☐ 2. Are excluded by the applicability clause or definition in the standard or by FDA written guidance.
  Specify reason for exclusion _____.
- ☐ 3. Are personal household goods of an individual entering the U.S. or being returned to a U.S. resident. (Limit: 3 of each product type).
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- ☐ 1. Last annual report or Product/Initial report

  _____ ACCESSION NUMBER of Report _____ Name of MANUFACTURER OF RECORD *(Filed report with FDA/CDRH)*

- ☐ 2. Unknown manufacturer or report number; State reason: _____

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SIGNATURE OF IMPORTER OF RECORD

NAME AND TITLE OF RESPONSIBLE PERSON

Public reporting burden for this collection of information is estimated to average 0.2 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.