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

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	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).
- ☐ 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

_____ ACCESSION NUMBER of Report

_____ 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

NAME AND TITLE OF RESPONSIBLE PERSON