

Country	Listed person and address	Federal Register citation and date of publication
RUSSIA .....	Rm 2309, 23/F, Ho King Comm Ctr, 2–16 Fayuen St., Mongkok, Kowloon, Hong Kong. JSC Voentelcom, Bolshaya Olenya Str. 15A, Moscow, Russia .....	79 FR [INSERT FR PAGE NUMBER], June 16, 2014.
	Nasosy Ampika, 3-ya Institutskaya St. Bld. 15, Moscow, Russia .....	79 FR [INSERT FR PAGE NUMBER], June 16, 2014.
	Nuclin LLC, Serebryakova Proezd 14, Moscow, Russia .....	79 FR [INSERT FR PAGE NUMBER], June 16, 2014.
	SDB IRE RAS, 1 Vvedenskogo Square, Fryazino, Russia .....	79 FR [INSERT FR PAGE NUMBER], June 16, 2014.
	Security 2 Business Academy, a.k.a. S2BA, a.k.a. Academy of Business Security, Deguninskaya Street 10, Moscow, Russia; and Novoslobodskaya Str. 14/19, Moscow, Russia.	79 FR [INSERT FR PAGE NUMBER], June 16, 2014.
UNITED ARAB EMIRATES ....	Dobair General Trading Co. LLC, P.O. Box 30239, Dubai, UAE .....	79 FR [INSERT FR PAGE NUMBER], June 16, 2014.
	Golden Business FZE, Warehouse #FZS1 AN08, Jebel Ali Free Zone, Dubai, UAE; and P.O. Box 263128, Dubai, UAE.	79 FR [INSERT FR PAGE NUMBER], June 16, 2014.
	World Heavy Equipment, Industrial Area 10, Ras Al Khaimah, UAE; and World Equipment Trading L.L.C, Industrial Area 10, Ras Al Khaimah, UAE.	79 FR [INSERT FR PAGE NUMBER], June 16, 2014.

**PART 758—[AMENDED]**

■ 3. The authority citation for 15 CFR Part 758 continues to read as follows:

**Authority:** 50 U.S.C. app. 2401 et seq.; 50 U.S.C. 1701 et seq.; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

■ 4. Section 758.1 is amended by adding paragraph (b)(8) to read as follows:

**§ 758.1 The Electronic Export Information (EEI) filing to the Automated Export System (AES)**

\* \* \* \* \*

(b) \* \* \*

(8) For all exports of tangible items subject to the EAR where parties to the transaction, as described in § 748.5(d) through (f) of the EAR, are listed on the Unverified List (Supplement 6 to Part 744 of the EAR), regardless of value or destination.

\* \* \* \* \*

Dated: June 11, 2014.

**Kevin J. Wolf,**

*Assistant Secretary for Export Administration.*

[FR Doc. 2014–14040 Filed 6–13–14; 8:45 am]

**BILLING CODE 3510–33–P**

**DEPARTMENT OF COMMERCE**

**Bureau of Industry and Security**

**15 CFR Part 748**

**[Docket No. 140406409–01]**

**RIN 0694–AG15**

**Amendments to Existing Validated End-User Authorizations in the People’s Republic of China: Samsung China Semiconductor Co. Ltd and Semiconductor Manufacturing International Corporation; Correction**

**AGENCY:** Bureau of Industry and Security, Commerce.

**ACTION:** Correcting amendment.

**SUMMARY:** Bureau of Industry and Security (BIS) published a final rule in the **Federal Register** on May 29, 2014 (79 FR 30713), amending existing authorizations in the Export Administration Regulations (EAR) for Validated End-Users (VEUs) Samsung China Semiconductor Co. Ltd. (Samsung China) and Semiconductor Manufacturing International Corporation (SMIC) in the People’s Republic of China. BIS is correcting an inadvertent typographical error in a citation included in the list of eligible items for SMIC in the May 29 final rule. BIS also makes a conforming change.

**DATES:** This correction is effective June 16, 2014.

**FOR FURTHER INFORMATION CONTACT:**

Karen Nies-Vogel, Chair, End-User Review Committee, Bureau of Industry and Security, U.S. Department of Commerce, 14th Street & Pennsylvania Avenue NW., Washington, DC 20230; by

telephone: (202) 482–5991, fax: (202) 482–3991, or email: *ERC@bis.doc.gov*.

**SUPPLEMENTARY INFORMATION:** Bureau of Industry and Security (BIS) published a final rule in the **Federal Register** on May 29, 2014 (79 FR 30713), which amended existing authorizations in the Export Administration Regulations (EAR) for Validated End-Users (VEUs) Samsung China Semiconductor Co. Ltd. (Samsung China) and Semiconductor Manufacturing International Corporation (SMIC) in the People’s Republic of China. Specifically, BIS amended Supplement No. 7 to Part 748 of the EAR to change the address of the facility used by Samsung China. In addition, BIS added a facility to the list of eligible destinations and an item to the list of eligible items for SMIC. BIS is correcting an inadvertent typographical error in the second citation included in the list of eligible items for SMIC in the May 29 final rule. BIS also makes a conforming change by updating the citation in the “**Federal Register Citation**” column in the entry for SMIC.

**List of Subjects 15 CFR Part 748**

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

Accordingly, part 748 of the EAR (15 CFR parts 730–774) is amended as follows:

**PART 748—[AMENDED]**

■ 1. The authority citation for 15 CFR part 748 continues to read as follows:

**Authority:** 50 U.S.C. app. 2401 et seq.; 50 U.S.C. 1701 et seq.; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66

FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 8, 2013, 78 FR 49107 (August 12, 2013).

**Supplement No. 7 to Part 748—  
[AMENDED]**

- 2. Supplement No. 7 to Part 748—Authorization Validated End-User (VEU): List of Validated End-Users, Respective Items Eligible for Export, Reexport and Transfer, and Eligible Destination is amended by:
- a. Removing “748.15” in the list of items in the “Eligible items (By ECCN)” column for “Semiconductor Manufacturing International Corporation” and add in its place “742.15”; and
- b. Adding the citation “79 FR [INSERT PAGE NUMBER], June 16, 2014” at the end of the list of citations in the “Federal Register Citation” column for “Semiconductor Manufacturing International Corporation”.

**Eileen M. Albanese,**

*Acting Director, Office of Exporter Services.*

[FR Doc. 2014–14041 Filed 6–13–14; 8:45 am]

**BILLING CODE 3510–33–P**

**DEPARTMENT OF HEALTH AND  
HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 878**

[Docket No. FDA–2014–N–0655]

**Medical Devices; General and Plastic  
Surgery Devices; Classification of the  
Nonabsorbable Expandable  
Hemostatic Sponge for Temporary  
Internal Use**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying the nonabsorbable expandable hemostatic sponge for temporary internal use into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the nonabsorbable expandable hemostatic sponge for temporary internal use classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

**DATES:** This order is effective July 16, 2014. The classification was applicable April 3, 2014.

**FOR FURTHER INFORMATION CONTACT:** Kelley Burridge, Center for Devices and

Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G425, Silver Spring, MD 20993–0002, 301–796–7630.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144, July 9, 2012), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the

device submitted is not of “low-moderate risk” or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.

On January 30, 2013, RevMedx, Inc., submitted a request for classification of XSTAT under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the de novo request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on April 3, 2014, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding § 878.4452.

Following the effective date of this final classification administrative order, any firm submitting a premarket notification (510(k)) for a nonabsorbable expandable hemostatic sponge for temporary internal use will need to comply with the special controls named in the final administrative order.

The device is assigned the generic name nonabsorbable expandable hemostatic sponge for temporary internal use, and it is identified as a prescription device intended to be placed temporarily into junctional, non-compressible wounds, which are not amenable to tourniquet use, to control bleeding until surgical care is acquired. The sponges expand upon contact with blood to fill the wound cavity and provide a physical barrier and pressure that facilitates formation of a clot. The device consists of sterile nonabsorbable radiopaque compressed sponges and