

U.S. Nuclear Regulatory Commission ATTN: Document Control Desk Two White Flint North Building 11545 Rockville Pike Washington, DC 20555 Attn: Mr. Keith McConnell

RE: License Amendment Request

**Transfer Control of License Number STB-401** 

Dear Mr. McConnell:

This letter and attachments constitute a request for amendment to the above referenced license for activities at the St. Louis, Missouri facility. This amendment request is necessitated as a result of the intercompany reorganization that resulted in Mallinckrodt Inc. being converted to a limited liability company, Mallinckrodt LLC. This transaction was completed on June 23, 2011

All other conditions relating to the subject license remain unchanged at this time.

This transaction was completed on June 23, 2011, and Mallinckrodt Inc. was converted to Mallinckrodt LLC, a Delaware limited liability company.

Documentation regarding the transaction is attached hereto in a letter to the NRC from Patricia Duft dated July 26, 2011. A completed NRC Form 313 is also attached for the above referenced license.

Please contact me at 314-654-5838 if you require additional information regarding this matter. Your prompt review and consideration of this license amendment request is appreciated.

Sincerely,

Karen Burke

Radiation Safety Officer

Karen Deuke.

Enc: Letter dated July 26, 2011 to NRC from Patricia Duft

Cc: John Buckley (NRC)

Alan Faust (Mallinckrodt)

F5ME20

### NRC FORM 313

U.S. NUCLEAR REGULATORY COMMISSION

APPROVED BY OMB: NO. 3150-0120

EXPIRES: (03/31/2012)

(1-2012) 10 CFR 30, 32, 33, 34, 35, 36, 39, and 40

### APPLICATION FOR MATERIALS LICENSE

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the Information Services Branch (T-5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, or by internet e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

### APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

OFFICE OF FEDERAL & STATE MATERIALS AND ENVIRONMENTAL MANAGEMENT PROGRAMS DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS U.S. NUCLEAR REGULATORY COMMISSION WASHINGTON, DC 20555-0001

### ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

### IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

### SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY U.S. NUCLEAR REGULATORY COMMISSION, REGION I 475 ALLENDALE ROAD KING OF PRUSSIA, PA 19406-1415

### IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION III 2443 WARRENVILLE ROAD, SUITE 210 LISLE, IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,

### SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH U.S. NUCLEAR REGULATORY COMMISSION, REGION IV 1600 E. LAMAR BOULEVARD ARLINGTON TX 76011-4511

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S.NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

| 4. THIS IS AN ADDUCATION FOR (Check engagists item)   |         |              |                 |  | 2 NAME A   | AND MAILING ADDRESS OF APPLICANT (Include ZIP code) |  |
|---|---------|--------------|-----------------|--|--|---|--|
| THIS IS AN APPLICATION FOR (Check appropriate item)   |         |              |                 |  | ' '  |   |  |
| A. NEW LICENSE  |         |              |                 |  | Mallinckrodt LLC   |   |  |
| D AMENDMENT TO LICENISE MUNIPER STB-401   |         |              |                 |  | 3600 N. Second Street  |   |  |
| B. AMENDMENT TO LICENSE NUMBER  STD-TOT   |         |              |                 |  | St. Louis, Missouri 63147  |   |  |
| C. RENEWAL OF LICENSE NUMBER  |         |              |                 |  |  |   |  |
| 3. ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED  |         |              |                 |  | 4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION   |   |  |
| N/A Standby Only license  |         |              |                 |  | Karen Burke  |   |  |
|   |         |              |                 |  | TELEPHONE NUMBER   |   |  |
|   |         |              |                 | (314) 654-5838                                       |  |   |  |
| SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.   |         |              |                 |  |  |   |  |
| <ol> <li>RADIOACTIVE MATERIAL         <ul> <li>Element and mass number; b. chemical and/or physical form; and c. maiximum amount which will be possessed at any one time.</li> </ul> </li> </ol>  |         |              |                 |  | 6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.  |   |  |
| INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE.   |         |              |                 |  | 8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.  |   |  |
| 9. FACILITIES AND EQUIPMENT.  |         |              |                 |  | 10. RADIATION SAFETY PROGRAM.  |   |  |
| 44 MASTE MANACEMENT   |         |              |                 | 12. LICENSE FEES (See 10 CFR 170 and Section 170.31) |  |   |  |
| 11. WASTE MANAGEMENT.   |         |              |                 |  | FEE CATEGORY 14A AMOUNT SOLUTION SOLUTI |   |  |
| 13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.  |         |              |                 |  |  |   |  |
| THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 39, AND 40, AND THAT ALL INFORMATION CONTANED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.  WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A C RIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION. |         |              |                 |  |  |   |  |
|   |         |              |                 |  | SIGNATUR   | E / D O / DATE                                      |  |
| Associate General Counsel Robert Budenholzer Cobert Budbulloff 2-9-12   |         |              |                 |  |  |   |  |
| FOR NRC USE ONLY V  |         |              |                 |  |  |   |  |
| TYPE OF FEE   | FEE LOG | FEE CATEGORY | AMOUNT RECEIVED | CHECK  | NUMBER   | COMMENTS  |  |
|   |         |              | \$              |  |  |   |  |
| APPROVED BY DATE  |         |              |                 |  |  |   |  |
|   |         |              |                 |  |  |   |  |



## Via Federal Express

July 26, 2011

U.S. Nuclear Regulatory Commission ATTN: Document Control Desk Two White Flint North Building 11545 Rockville Pike Washington, DC 20555

#### Consent to Transfer Control of License Number STB-401 RE:

Dear Mr. Buckley:

This letter is to follow up on Mallinckrodt's letters dated May 27, 2011 and July 7, 2011 regarding the Mallinckrodt Inc. intercompany reorganization that resulted in Mallinckrodt Inc. being converted into a limited liability company, Mallinckrodt LLC. This transaction was completed on June 23, 2011, and Mallinckrodt Inc. was converted to Mallinckrodt LLC, a Delaware limited liability company.

As requested in your letter dated July 7, 2011, Mallinckrodt LLC is providing confirmation that the transaction was completed and is providing the following additional information.

1. Provide a complete description of the transaction.

As part of an internal transaction of Covidien plc subsidiaries, Mallinckrodt Inc., a Delaware corporation was converted to Mallinckrodt LLC, a Delaware limited liability corporation. The following is a simplified summary of the proposed steps: (1) Mallinckrodt Inc. filed a certificate of conversion under Delaware law to convert the company into a limited liability company; (2) after the conversion to a limited liability company, the entity was renamed as Mallinckrodt LLC; and (3) Mallinckrodt LLC maintained ownership of legal title to the plants and equipment subject to the licenses noted above. None of these transactions involved any legal entities which were not affiliated with Mallinckrodt Inc. All of the movement of assets and ownership was within the group of companies all wholly owned directly or indirectly by Covidien plc. Attached as Exhibit "A" to this letter are copies of the corporate documents filed with the Delaware Secretary of State. The new name of the licensed organization is Mallinckrodt LLC. Its headquarters address will remain at the current location.



Mallinckrodt LLC 675 McDonnell Blvd Hazelwood, MO 63042

The new licensee contact and telephone number(s) will remain the same;

Patricia H. Duft Vice-President, Legal 675 McDonnell Blvd. Hazelwood, MO 63042 Phone: 314-654-6314

E-mail: Pat.Duft@Covidien.com

Karen Burke (License STB-401) Radiation Safety Officer 675 McDonnell Blvd. Hazelwood, MO 63042 Phone 314-654-5838

E-mail: Karen.Burke@Covidien.com

2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience of for new personnel.

There are no changes to the licensed program. Mallinckrodt LLC has the same Radiation Safety Officer as Mallinckrodt Inc. A listing of the Mallinckrodt LLC managers and officers is attached hereto as **Exhibit** "B".

3. Describe any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.

No changes.

4. Describe the status of the surveillance program (surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.

There are no changes to any of the surveillance programs and all will be maintained in the same manner. There will be no changes in location of records. All pertinent and required records applicable to licensed operations will be retained at the transferee's location at the time the conversion is completed.

5. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to the NRC, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity. A copy of the amended Letter of Credit dated June 23, 2011 in the new name is attached as Exhibit "C".

Refer to the response offered in Item 4. There is no change to the decommissioning cost estimate necessary.

6. Confirm that the transferee will abide by all constraints, conditions, requirements and commitments of the transferor.

All of the existing license conditions will be maintained, and constraints, conditions, requirements, representations and commitments identified in the above referenced licenses will be followed by Mallinckrodt LLC upon conversion of the Mallinckrodt Inc. to Mallinckrodt LLC. All of the existing radiation safety programs will be maintained and followed as required by applicable license conditions and regulation.

7. Documentation that the transferor and transferee agree to the change in ownership or control of the licensed material and activity, and the conditions of transfer; and the transferee is made aware of all open inspection items and its responsibility for possible resulting enforcement actions.

Mallinckrodt Inc. has agreed to the conversion to Mallinckrodt LLC. Refer to filings with the Delaware Secretary of State attached hereto as **Exhibit "A".** There are currently no open inspection items.

This submittal completes the required information in accordance with RIS 2008-19. Please note that Ms. Karen Burke will be preparing a License Amendment requesting the license be revised to note the new Mallinckrodt LLC name. I trust we have addressed all of the questions documented in your letter of July 7, 2011. If you have any further questions, please contact Ms. Karen Burke at 314-654-5838. Thank you for your assistance in this process.

Sincerely,

Patricia H. Duft

Karen Berke

Enc:

Exhibit "A"- Secretary of State Documentation Exhibit "B"-Manager and Officer List Exhibit "C"-Letter of Credit

Cc: John Buckley (NRC)

Karen Burke (Mallinckrodt)

Kay Yoder (Mallinckrodt)

# Exhibit A

# Delaware

# The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE DO HEREBY CERTIFY THAT THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF CONVERSION OF A DELAWARE CORPORATION UNDER THE NAME OF "MALLINCKRODT INC." TO A DELAWARE LIMITED LIABILITY COMPANY, CHANGING ITS NAME FROM "MALLINCKRODT INC. " TO "MALLINCKRODT LLC", FILED IN THIS OFFICE ON THE TWENTY-THIRD DAY OF JUNE, A.D. 2011, AT 8:40 O'CLOCK A.M.

2161269 8100V

AUTHENTICATION: 8855800

DATE: 06-23-11

09:22

State of Delaware Secretary of State Division of Corporations Delivered 08:24 AM 06/23/2011 FILED 08:40 AM 06/23/2011 SRV 110749598 - 2161269 FILE

## CERTIFICATE OF CONVERSION FROM A CORPORATION TO LIMITED LIABILITY COMPANY

Pursuant to Sections 18-204 and 18-214 of the Delaware Limited Liability Company Act

- 1. The name of the corporation immediately prior to the filing of this Certificate of Conversion to Limited Liability Company is Mallinckrodt Inc.
- 2. The corporation was originally incorporated on the 19th day of May, 1988 under the laws of the State of Delaware.
- 3. The name of the limited liability company into which the corporation shall be converted, as set forth in its Certificate of Formation, is Mallinckrodt LLC.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the undersigned authorized person has caused this Certificate of Conversion to be executed this 23rd day of June, 2011.

Vame: Whn W. Kapples litle: Authorized Officer

[Signature Page to Certificate of Conversion to LLC for Mallinckrodt Inc.]

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# Delaware

# The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE DO HEREBY CERTIFY THAT THE ATTACRED IS A TRUE AND CORRECT COPY OF CERTIFICATE OF FORMATION OF "MALLINCKRODT LLC" FILED IN THIS OFFICE ON THE TWENTY-THIRD DAY OF JUNE, A.D. 2011, AT 8:40 O'CLOCK A.M.

110749598

You may verify this certificate online at corp.delaware.gov/authver.shtml

AUTHENTY CATION: 8855800

DATE: 06-23-11

Ø8:22

State of Delaware Secretary of State Division of Corporations Delivered 08:24 AM 06/23/2011 FIED 08:40 AM 06/23/2011 SRV 110749598 - 2161269 FILE

## CERTIFICATE OF FORMATION

OF

## MALLINCKRODT LLC

- ı. The name of the limited liability company is Mallinckrodt LLC.
- The address of its registered office in the State of Delaware is 1209 Orange Street, in the City of Wilmington, County of New Castle. The name of its registered agent at such address is The Corporation Trust Company.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the undersigned has executed this Certificate of Formation this 23rd day of June, 2011.

Name: John W. Kapples Title: Authorized Person

# Exhibit B

# MANAGEMENT BOARD

Robert T. Budenholzer Joseph A. Wuestner Peter G. Edwards

# **OFFICERS**

Richard J. Meelia Richard G. Brown Charles J. Dockendorff Peter G. Edwards John W. Kapples Kevin G. DaSilva Lisa K Golod Woodrow Howell Geoffrey Kupferschmid Stephen C. Carey Eric C. Green John H. Masterson Jeffrey S. Boone Patricia Hitt Dust Kenneth D. Goetz Robert T. Budenholzer Matthew J. Nicolella Lawrence T. Weiss Joseph A Wuestner C. Stephen Kriegh Matthew K. Harbaugh Kathleen A. Schaefer Christine Rebman Cooke Stephanie Kardasz Jerad G. Seurer Deborah L. Davis Brian D. Lefort Donald A Lohman

President Vice President Vice President Vice President Vice President Vice President & Treasurer Vice President & Assistant Treasurer Vice President & Secretary Vice President & Assistant Secretary Vice President & Chief Financial Officer Vice President & Controller Assistant Secretary Assistant Secretary Assistant Secretary Assistant Secretary Assistant Secretary Assistant Secretary