



# SUPPLIER CHANGE REQUEST PORTAL **OVERVIEW AND TRAINING**

**Global Supplier Quality**  
**March 2022**

[RS.changeportalhelp@medtronic.com](mailto:RS.changeportalhelp@medtronic.com)

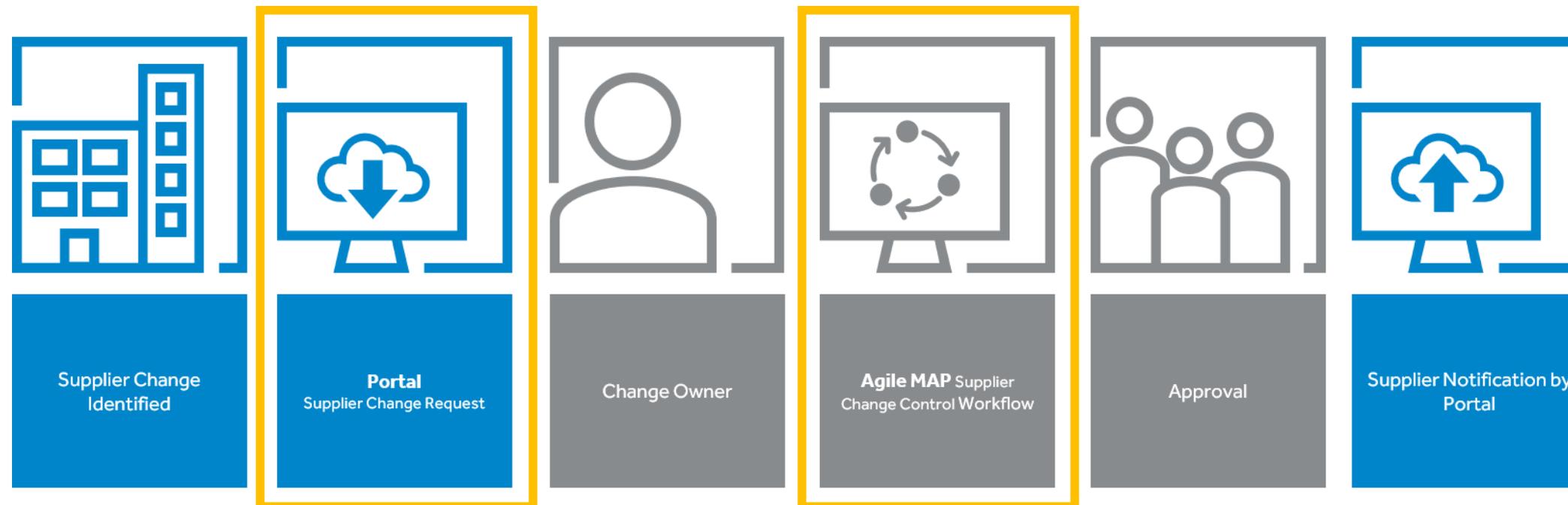
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Further, Together  
**Medtronic**

# SUPPLIER CHANGE REQUEST PORTAL OVERVIEW

- Overview
- Portal Purpose and Use
  - Purpose of system
  - Accessing system
  - Create a change request
  - Medtronic processing of change

# SUPPLIER CHANGE REQUEST PORTAL OVERVIEW

- Started in 2015
  - First step beyond paper and manual tracking for Supplier Change Control
- Continuous Improvement
  - Portal enhancements to streamline collection of information from suppliers
  - Medtronic process changes to support suppliers and internal assignments
  - Moving toward one supplier change control process across all Medtronic
- Medtronic changes focused on faster responses to suppliers



# PURPOSE OF SYSTEM



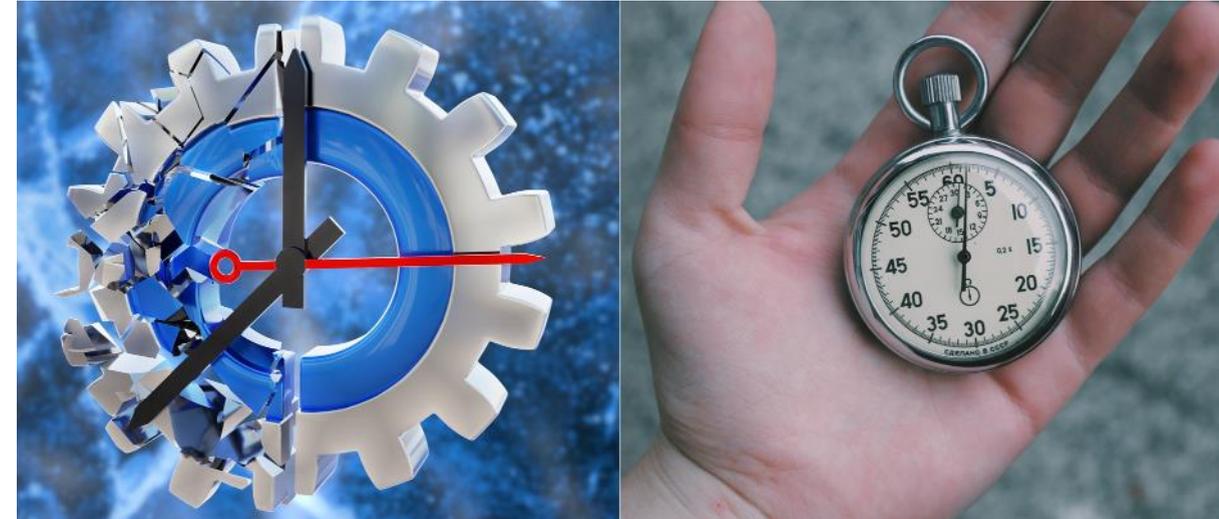
# ROLE OF THE SUPPLIER

- Submit changes within Supplier Change Request Portal with adequate advanced notification
  - Routine review – expect weeks
  - Complex review – expect months
- Establish an effective supplier process for triggering notification of changes to Medtronic
- If applicable, define proactive process to identify and communicate changes from sub-tier suppliers

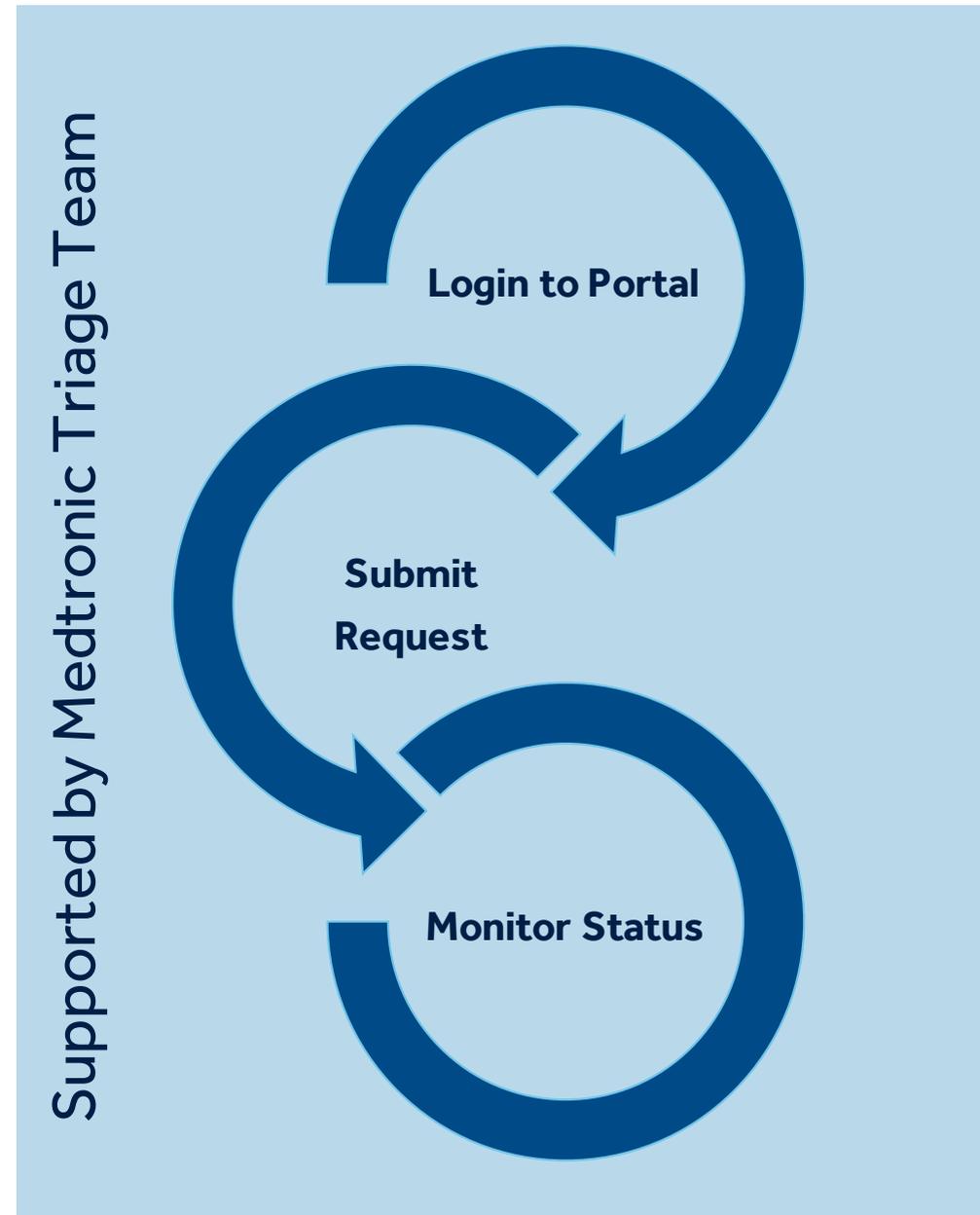


# ENHANCEMENTS & CONTINUOUS IMPROVEMENT

- Enhancements focus on predictable time to complete routine review
  - New and updated fields completed by suppliers for Medtronic to disposition from first touch
  - Central team review and expedite to the operating unit
  - Metrics to monitor backlog
  
- Continuous improvement cycles
  - Learn from latest effort
  - Visibility to backlog, drive future improvements



# EASY STEPS FOR SUPPLIER



1. Login into website:  
[changerequest.medtronic.com](https://changerequest.medtronic.com)
2. Complete Change Request (SCR) & submit
3. Central team may follow-up with supplier
4. Monitor Status - Medtronic will send you email notifications for the following:
  - a) Weekly reminders of items in draft status
  - b) Receipt of original request
  - c) Status updates
  - d) If needed – Request for more information
  - e) Approval or disapproval of change and close notice, when last facility completes review

# SUPPLIER BENEFITS

- Standardized submission process for all operating units within Medtronic
- Standard web form and content requirements to submit change request
- Visibility and notification of status updates across all operating units – enhanced color coding
- Traceability to submitted changes
- Tied to new Medtronic functionality with progress toward adoption by all operating units and facilities

The screenshot displays the 'SUPPLIER CHANGE REQUEST' portal. At the top, there are navigation tabs for 'My Requests', 'New Request', and 'Account Information'. Below this, the page title is 'Request 114639 - Change Request Sample'. On the left, a 'REQUEST SECTIONS' sidebar shows 'Request Status' and 'Supplier Information' with green checkmarks, and a 'Review Request' link. The main area, 'MEDTRONIC AFFECTED FACILITIES', lists three facilities with their change status:

Facility	Change Owner	Status
Cardiac Rhythm Management Medtronic CryoCath LP, Pointe-Claire, Canada	John Dela Cruz	Approved
Diabetes Diabetes - Northridge, Northridge, United States	John Dela Cruz	Disapproved
Medtronic Puerto Rico Ops - Juncos, Juncos, United States	John Dela Cruz	Not Applicable

# ACCESSING THE SYSTEM

# SUPPLIER CHANGE REQUEST (SCR) PORTAL SIGN IN

- Visit URL: [changerequest.medtronic.com](https://changerequest.medtronic.com)
  - First time users need to create an account
  - Chrome is the preferred web browser
  - Troubleshooting Steps for issues with error message in the SCR Portal:
    1. Use Chrome as browser
    2. Clear cache and cookies, then re-launch browser
    3. Access the SCR portal at <https://wwwp.medtronic.com/changerequest/public/landingPage>
    4. Log back in using registered email and password

Medtronic English

## SECURED ACCESS

### SIGN IN

EMAIL (or Medtronic employee username)

PASSWORD

Show Password

[Forgot Password](#)

Don't have a Medtronic account? [Create one.](#)

© Medtronic

# INITIAL REGISTRATION

First-time users must register and create an account

- Provide contact information
- You can manage and reset your own password

**Medtronic** English

## SECURED ACCESS

### CREATE YOUR MEDTRONIC ACCOUNT

Create an account to access Medtronic sites and services.

\* Indicates a required field

\* COUNTRY/REGION  
Select One

\* FIRST NAME \* LAST NAME

\* E-MAIL ADDRESS

\* PASSWORD  Show Password

Use 8 or more characters with a mix of upper and lowercase letters, and at least 1 number.

\*  I have read and accept the Privacy Statement.

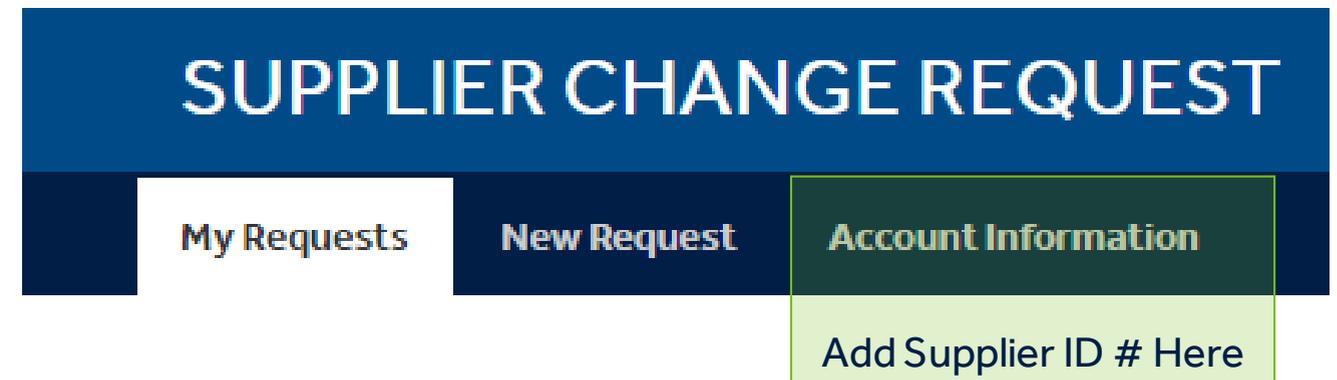
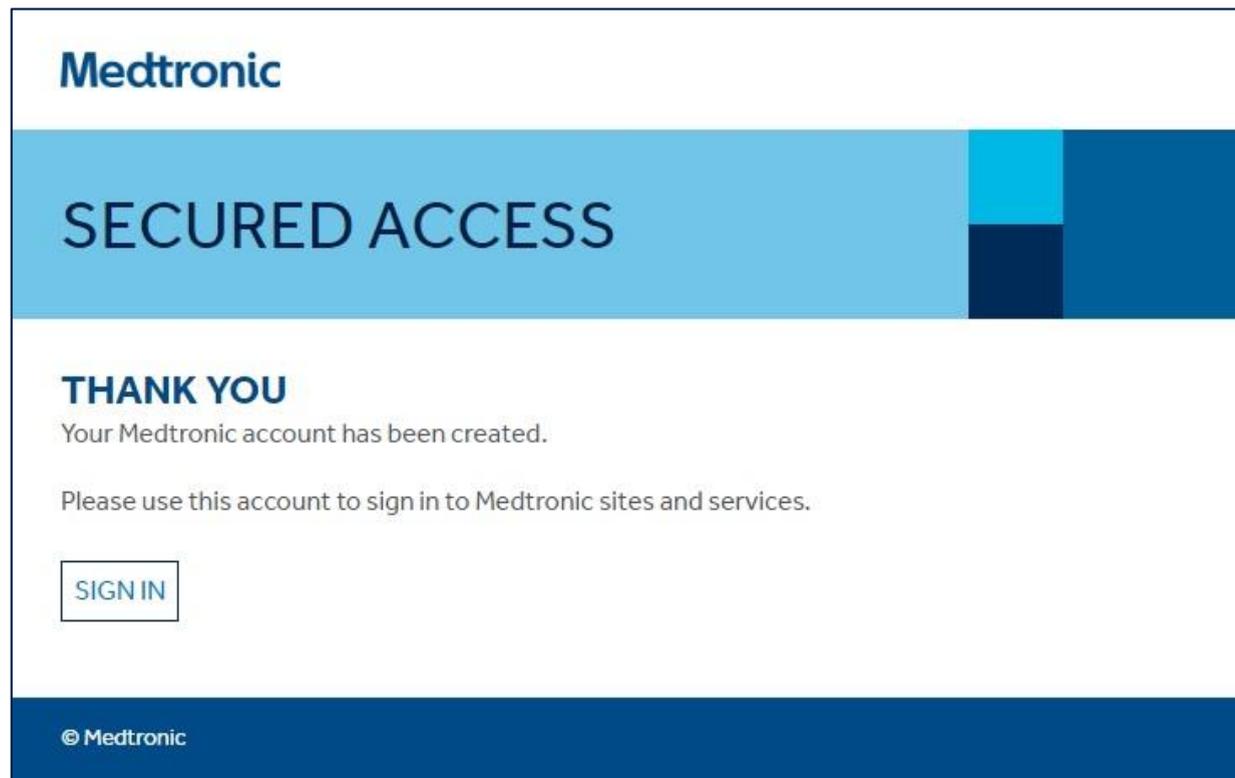
**CREATE ACCOUNT**

Already have an account? [Sign in](#)

© Medtronic

# COMPLETING THE REGISTRATION PROCESS

- Proceed to Sign In
- Medtronic Supplier ID is listed on the PO; this field is optional in Account Information
- Each user must register separately; there is no “shared” view within a supplier



# UPDATING YOUR ACCOUNT INFORMATION

## AFTER INITIAL REGISTRATION

- Supplier can modify account information to update business name, business phone, and Medtronic ID.
- Use the Account Information tab to update and click submit to save changes.
- Check your purchase order or contact your Medtronic Quality partner to get your supplier ID.

### SUPPLIER CHANGE REQUEST

[My Requests](#)   [New Request](#)   [Account Information](#)

#### My Account Information

Account information saved.

Supplier Company Name:	<input type="text" value="Training Company"/>
Supplier Company Phone:	<input type="text" value="(800) 633-8766"/>
Medtronic Supplier ID:	<input type="text" value="Train000123"/>

# LOCATING YOUR MEDTRONIC SUPPLIER ID FROM PURCHASE ORDER

## EXAMPLE 1

**Medtronic**  
 Medtronic Facility Name  
 111 Sample Street  
 Sample City, Sample State

**Purchase Order**

PURCHASE ORDER 4504394531	REV 0
------------------------------	----------

07/23/2019  
Page 1 of 7

**TO: 100000**  
 Vendor Company  
 111 Sample Street  
 Sample City, Sample State

**SHIP TO:** Medtronic Facility Name  
 111 Sample Street  
 Sample City, Sample State

**BILL TO:** Company Name  
 111 Sample Street  
 Sample City, Sample State

For Invoice Inquiries:

Vendor Contact Person:	Fax:	Fax: 555-555-5555
Buyer Name: Sample Name	Fax: 555-555-5555	Fax:
Incoterms: FOB Shipping Point	Currency: USD	

Payment Terms: Net 30  
 ORDER BASED ON 23-Jul-19 DEMAND / SHIP ORDER, SHIP PER SIGNALS

For shipments less than 100 LBS ship via FedEx International Economy a/c# 27470737  
 Alternate Carrier: UPS Second Day a/c# 899022915

For shipments more than 100 LBS ship via FedEx International Economy Freight a/c# 27470737  
 Alternate Carrier: UPS SurePost Solution Second Day a/c# 70813722

If your Purchase Order looks like this:

Your Medtronic Supplier ID is here.

Your Medtronic Ship-to Address is here.

## EXAMPLE 2

**HeartWare**  
 Medtronic Facility Name  
 111 Sample Street  
 Sample City, Sample State

www.heartware.com

Ph: +1-  
Fax: +1-

Vendor Company  
 111 Sample Street  
 Sample City, Sample State

Purchase Order	Rev	Order Date	Print Date
45998	0.00	2019-07-22	2019-07-23

Supplier: 60000100

Ship-To: 1000

**Purchase Order**

Medtronic Facility Name  
 111 Sample Street  
 Sample City, Sample State

Medtronic INC  
 PO Box 776  
 Minneapolis, MN 55440  
 rs.usap@medtronic.com

Buyer	Contact	Telephone
Sample Buyer Name		555-555-5555
Payment Terms	Ship Via	POB
Net 30 Days	UPSGRND	Origin

Remarks: UPS SurePost Solution Second Day a/c# 70813722

If your Purchase Order looks like this:

Your Medtronic Supplier ID is here.

Your Medtronic Ship-to Address is here.

# SCR HOME SCREEN

- **My Requests**–view requests submitted by user
  - **Request ID** – number assigned to request; click to display details
  - **Title** – description entered in the change details screen
  - **Submitted Date**– The date the SCR was submitted
  - **Implementation Date**– Requested date of review completion and work begins
  - **Status**– Operating Unit(s) affected and corresponding stage(s) of evaluation (*see next slide*)
- **New Request** – enter a new change request or update a request returned “More Information Requested”
- **Account Information** –update Supplier Name and number.

**SUPPLIER CHANGE REQUEST**

My Requests | New Request | Account Information

Filter By:

Request ID:  Title:  Submitted Date:  Implementation Date:  Operating Unit:  Change Request Status:  Operating Unit Status:

APPLY FILTER(S) REMOVE FILTER(S)

Request ID	Title	Submitted Date	Implementation Date	Status
<a href="#">114639</a>	Change Request Sample	2021-Jun-28	2021-Nov-17	Diabetes: Disapproved Cardiac Rhythm Management: Approved

1 change request

Help  
• For portal support, view the [Help Guide](#);  
• For information about a specific change request, contact your Medtronic sourcing partner;  
• For general assistance email [rs.changeportalhelp@medtronic.com](mailto:rs.changeportalhelp@medtronic.com)

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# SCR PORTAL STATUS OVERVIEW

- **Draft** – the status that indicates a change notice has been started, but not submitted to Medtronic. **Draft change requests are only visible to the person who initiates the request** (i.e., Supplier)
- **Unassigned** means a change owner needs to be assigned for each facility/operating unit.
- **Under review** means one or more facilities/operating units are working on the change request.
- **Approved, Disapproved, Not Applicable** – indicate a facility has completed its review.
  - **Email notice sent – Closed request** – All assigned operating units and their facilities have completed a final disposition for their portion of the change. Email notice will tell you it is closed and proceed.
- **More Information Requested** means that Medtronic has requested the SCR be updated by the supplier. Look for notes about what is requested. **The supplier must make the revisions and re-submit the same SCR for the process to continue.**
- **Closed** – receive email, disappears from queue, use drop down to see closed

The screenshot shows a portion of the SCR Portal interface. At the top, there are two blue buttons: "APPLY FILTER(S)" and "REMOVE FILTER(S)". Below these are two dropdown menus. The first is labeled "Change Request Status" and has a dropdown menu open showing the options: "Open", "Open", "Closed", and "Draft". The second is labeled "Operating Unit Status" and has a dropdown menu with the option "All". Below the dropdowns is a horizontal bar with a grey background and the text "Disapproved" on the right side.

# SYSTEM NOTICE – ITEM IN DRAFT

## RECEIVED ONLY BY SUPPLIER CONTACT WHO ENTERED DRAFT

### Reminder - Your Medtronic Change Request (SCR) is still in Draft state

noreply@medtronic.com <noreply@medtronic.com>

Thu 1/9/2020 5:31 PM

To: RS Testing Room <rs.testingroom@medtronic.com>

You have the following change request(s) still pending in the draft state in the Medtronic Supplier Change Request Portal.

SCR Number	SCR Title	Date Created	Status
<a href="#">114407</a>	none	2019-Dec-06	Draft
<a href="#">114376</a>	none	2019-Nov-25	Draft
<a href="#">114371</a>	draft without submitting	2019-Nov-22	Draft

Any SCR showing a status of **Draft** is only visible to you as the requestor and Medtronic is unable to view or act on these requests. If you no longer need the SCR you may delete it from the system at any time while it is in a Draft status. If you thought you had already submitted the request please review the SCR for any missing information and progress it to the Submit page.

For general help about this system you may contact us at [rs.changeportalhelp@medtronic.com](mailto:rs.changeportalhelp@medtronic.com). For status of a previously submitted SCR please contact your Medtronic change owner listed on the SCR. Thank you for using the **Medtronic Supplier Change Request System**.

You can access your change request(s) at the following link using your system login and password:  
<https://wwwp-test.medtronic.com/changerequest>

# CREATE A CHANGE REQUEST

# WRITING TIPS FOR COMPLETING YOUR SUPPLIER CHANGE REQUEST

- Use clear, concise language
- Use terms anyone can understand
- Spell out acronyms which may be unknown to Medtronic or which may have multiple meanings
- Avoid jargon your company or geographic region may be using
- Communicate with your Medtronic Point of Contact for questions



- ✓ Be factual and clear
- ✓ State the change without adding opinions or your interpretation of risk

# CONTENT NEEDED FOR A CHANGE REQUEST

## Change Details

- Information to describe the change and reason(s) why the change is being made

## Change Evaluation

- What has been done to evaluate the change and effect on product performance

## Medtronic Affected Facilities

- What Medtronic sites and operating units will be impacted by the change
- The timing associated with the change

## Supplier contact information

- Name, email address, phone number etc.

## BEFORE YOU PROCEED

### INFORMATION YOU'LL NEED TO HAVE AVAILABLE

- Purchase Orders which identify Medtronic Ship-to Facilities
- Feedback from central team, if requested, to help you select Medtronic Facilities
- Supporting materials such as part numbers, diagrams of manufacturing facility or part or any attachment that clarifies the request
- Preferred Medtronic Contact (optional)



# CHANGE DETAILS

- Click on the **New Request** tab and complete the required fields shown in red.
- Complete all four sections of the form
  - Change Details
  - Change Evaluation
  - Medtronic Affected Facilities
  - Supplier Information: *pre-populated based on registration information*

*Note: Required fields*

*identified with an \* must be completed to submit form.*

The screenshot displays the 'SUPPLIER CHANGE REQUEST' form. At the top, there are three tabs: 'My Requests', 'New Request' (which is selected), and 'Account Information'. Below the tabs, the form is divided into two main sections: 'REQUEST SECTIONS' on the left and 'CHANGE DETAILS' on the right. The 'REQUEST SECTIONS' section contains a list of links: 'Change Details' (highlighted in blue), 'Change Evaluation', 'Medtronic Affected Facilities', 'Supplier Information', and 'Review and Submit'. Below this list is a 'delete request' button. The 'CHANGE DETAILS' section contains the following fields and instructions:

- A red asterisk indicates required information.
- Change Title**: A red-bordered text input field. Below it, the instruction reads: 'Provide a brief title for the change (e.g. Change of raw material supplier, Use As Is disposition request, Planned Deviation request)'.
- Medtronic Part Number / Rev**: A section with the instruction 'List or attach the Medtronic Part Number(s) affected by this change and current Revision.' Below this are radio buttons for 'List' (selected) and 'Attach'.
- A table for entering part numbers and revisions:

Medtronic Part Number	Revision
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>
<input type="text"/>	<input type="text"/>

Below the table is a '+ Add Another' link.

# COMPLETING A CHANGE REQUEST

## CHANGE DETAILS

- *Change Title*

- *Medtronic Part Numbers*

- Additional rows can be added (or removed). Alternately, a file of part numbers can be attached

- *Change Type*

- Check all that apply
- “Hover Over” to see detail description of Change Types

**\* Change Title**

Provide a brief title for the change (e.g. Change of raw material supplier, Use As Is disposition request, Planned Deviation request)

**Medtronic Part Number / Rev**

List or attach the Medtronic Part Number(s) affected by this change and current Revision.

List  Attach

**Medtronic Part Number**

<input type="text"/>	Revision	<input type="text"/>	
<input type="text"/>	Revision	<input type="text"/>	X
<input type="text"/>	Revision	<input type="text"/>	X

[+ Add Another](#)

**\* Change Type**

Identify the applicable Change Type (check all that apply).

<input type="checkbox"/> Business - Name or Ownership change	<input type="checkbox"/> Equipment, Tooling, Molds	<input type="checkbox"/> Manufacturing Process
<input type="checkbox"/> Component Labeling	<input type="checkbox"/> Facility/Address	<input type="checkbox"/> Material
<input type="checkbox"/> Component Packaging	<input type="checkbox"/> Finished Device Labeling	<input type="checkbox"/> Product Software
<input type="checkbox"/> Control Plan or Sampling Plans	<input type="checkbox"/> Finished Device Packaging	<input type="checkbox"/> Quality System
<input type="checkbox"/> Design	<input type="checkbox"/> Inspection/Test Methods	<input type="checkbox"/> Sterilization/Microbiology
<input type="checkbox"/> Temporary Change (Use As Is, Planned Deviation)		

# COMPLETING A CHANGE REQUEST

## CHANGE DETAILS - CONTINUED

- *Change Description*
  - *From/To statements that describe the change*
  
- *Reason for Change*
  - Check a box or multiple
  - Describe reason in text field
  
- *Supporting Documentation*
  - Attach files or reports that show evidence of the change or further background of the change

### \* Change Description

Describe in detail WHAT is changing. Clearly outline the current and future state (From / To). Outline what documentation would be impacted by the change (e.g. specifications, Control Plan, FMEA). Outline if the change is part of a large or multiple phase project plan. If needed, include additional detail in clearly identified attachments. If there are multiple changes, list and number each change separately as a From/To (1, 2, 3, etc).

### \* Reason for Change

Select any reason that applies.

- |   |  |   |
|---|--|---|
| <input type="checkbox"/> Continuous Improvement             | <input type="checkbox"/> Management/Business Related | <input type="checkbox"/> Medtronic Initiated Change |
| <input type="checkbox"/> Cost Savings                       | <input type="checkbox"/> Material Availability       | <input type="checkbox"/> Response to Audit finding  |
| <input type="checkbox"/> Response to Medtronic CAPA         |  |   |
| <input type="checkbox"/> Sub-tier Supplier Initiated Change |  |   |

\* Please provide more information on the reason for change in the text field.

Rich text editor toolbar with buttons for Bold (B), Italic (I), Underline (U), Bulleted List, Numbered List, Indent, and Outdent. Below the toolbar is a large empty text area for providing more information on the reason for change.

### Supporting Documentation

Add any documentation impacted by the change or any information that further describe the change.

[+ Add file](#)

# COMPLETING A CHANGE REQUEST

## CHANGE EVALUATION

### ■ Risk Assessment

- Updated product or process risk documentation

### ■ Evaluation of Change

- Plan for testing and supporting evidence

### ■ Requested Date of Implementation

- Date requesting to implement for Medtronic
- Impact to production – date supplier or Medtronic production would be impacted
- Describe any risks to production supply

#### \* Risk Assessment

Provide an assessment of the risk associated with this change, including impact to part, product, performance, and business risk to supply continuity. Document if Design FMEA or Process FMEA were reassessed as a result of this change and provide as supporting evidence if applicable.

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#### \* Evaluation Of Change

Provide a description of how the change will be evaluated. How will you determine the impact of the change on the performance of the part you provide to ensure that form, fit or function is not impacted (i.e. characterization and qualification)? Describe or attach your plan for qualification of the change. If you have determined that qualification is not required, provide rationale.

#### \* Requested Date of Implementation

Provide the proposed date the supplier would like to implement the requested change(s).

#### Impact to Production

No  Yes

Date of Impact

\* What is the risk to the production (supply continuity) and what steps have been taken to mitigate risks?

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# SELECTING ACCURATE MEDTRONIC FACILITIES

- Reference purchase orders from Medtronic to identify
  - Your Medtronic Supplier ID
  - Medtronic Shipping Address
- “What is this?” in the portal shows example Purchase Orders
- When searching for facility, start typing on any fields and select from the options that appear. Keep other fields blank and hit search

The screenshot displays the 'SUPPLIER CHANGE REQUEST' portal. The main navigation bar includes 'My Requests', 'New Request', and 'Account Information'. The current page is 'Request 114641 -'. The left sidebar shows 'REQUEST SECTIONS' with 'Change Evaluation' and 'Medtronic Affected Facilities' highlighted, and a 'delete request' button. The main content area is titled 'MEDTRONIC AFFECTED FACILITIES' and includes a 'Search for Facilities' button. A modal window titled 'Search for Facilities' is open, showing a form with fields for 'Ship-to Address', 'City', 'State / Province', 'Country', 'Medtronic Operating Unit', and 'Facility Name'. A 'SEARCH' button and a 'cancel' link are at the bottom of the modal. A 'SAVE DRAFT' button is visible in the bottom right corner of the main content area. The footer contains a 'Help' section with links to the 'Help Guide' and 'Terms Of Use', and a copyright notice for Medtronic.

**1** Change Evaluation  
**2** Medtronic Affected Facilities  
**3** Search for Facilities

Request 114641 -

REQUEST SECTIONS

- Change Details
- Change Evaluation
- Medtronic Affected Facilities
- Supplier Information
- Review and Submit

delete request

MEDTRONIC AFFECTED FACILITIES

- \* indicates required information
- \* Medtronic Facility and Operating Units will be affected by this change.
- Indicate which Medtronic Facility and Operating Units will be affected by this change.
- Search for Facilities

Preferred Medtronic Contact(s)  
If you typically work with a specific Medtronic contact, please provide their name here.

< PREVIOUS    NEXT >

Search for Facilities

Please indicate which Medtronic facilities the product is shipped to.

Ship-to Address [What is this?](#)

City    State / Province    Country

Medtronic Operating Unit    Facility Name

SEARCH    cancel

SAVE DRAFT

Help

- For portal support, view the [Help Guide](#).
- For information about a specific change request, contact your Medtronic sourcing partner;
- For general assistance email [rs.changeportalhelp@medtronic.com](mailto:rs.changeportalhelp@medtronic.com).

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# LOCATING ACCURATE FACILITIES FROM PURCHASE ORDER

## EXAMPLE 3

PUR5000 Purchase Order Number: 20151157 Page 1 of 2  
 Print Date 2019-02-19  
 Invoice To Address Number 1002000 BILL to: COMPANYNAME  
 1002000 Vendor Company  
 111 Sample Street  
 Sample City, Sample State  
 Revision Date 2019-02-07  
 Rev: 1  
 Vendor Address: 1002000  
 Vendor Company  
 111 Sample Street  
 Sample City, Sample State  
 Ship To Address  
 Medtronic Facility Name  
 111 Sample Street  
 Sample City, Sample State  
 Terms: NET 60 DAYS Currency: USD FOB: FOB: ORIGIN  
 Ship Via: 502: USE COMPANY GUIDELINE  
 Supplier must have PPAP approval in writing from Medtronic prior to shipping against this PO. Contact the buyer before each shipment to confirm the latest revision, quantity and dock date. SC

If your Purchase Order looks like this:

Your **Medtronic Supplier ID** is here.

Your **Medtronic Ship-to Address** is here.

- Use "Ship To" city and/or street address to search and select accurate facilities
- Purchase orders list this information in different locations

**Search for Facilities** close

Please indicate which Medtronic facilities the affected product is shipped to.

Ship-to Address [What is this?](#)

City State / Province Country

Medtronic Operating Unit Facility Name

All

SEARCH cancel

## EXAMPLE 4

R55435008 THC00031 Purchase Order Print Order Number 727976000 XO Page - 1 of 1  
 Invoice To Address 02000 COMPANY NAME  
 111 SAMPLE STREET  
 SAMPLE CITY, SAMPLE STATE  
 Branch/Plant 310  
 Vendor 1002000  
 VENDOR COMPANY  
 111 SAMPLE STREET  
 SAMPLE CITY, SAMPLE STATE  
 Ship To 3000100  
 MEDTRONIC FACILITY NAME  
 111 SAMPLE STREET  
 SAMPLE CITY, SAMPLE STATE  
 Print Date December 11-2018  
 Terms NET 90 Currency Code USD Delivery  
 Base Currency USD Freight

If your Purchase Order looks like this:

Your **Medtronic Supplier ID** is here.

Your **Medtronic Ship-to Address** is here.

# CHANGE REQUEST PAGES - MEDTRONIC AFFECTED FACILITIES

- **Search and select the Medtronic location(s) that are impacted by the change**
  - Tip: Identify the Medtronic locations the product is shipped to or the service is provided for
- In addition to location, you must identify an Operating Unit so that the change request is routed properly within Medtronic.
  - If the operating unit is not known, ask your Medtronic contact
  - Or Submit the request and email triage your Request ID and ask for second review  
[RS.ChangePortalHelp@Medtronic.com](mailto:RS.ChangePortalHelp@Medtronic.com)
- Central team review validates selected Operating Units

**1** Search for Facilities close

Please indicate which Medtronic facilities the affected product is shipped to.

Ship-to Address [What is this?](#)

City State / Province Country

Medtronic Operating Unit Facility Name

All

SEARCH [cancel](#)

**3** Search for Facilities close

Facility Name	Street Address	City	State / Province	Country
<input checked="" type="checkbox"/> Medtronic CryoCath LP	9000 Autoroute Transcanadienne	Pointe-Claire	QC	Canada

ADD [cancel](#)

**2** Search for Facilities close

Please indicate which Medtronic facilities the affected product is shipped to.

Ship-to Address [What is this?](#)

City State / Province Country

Medtronic Operating Unit Facility Name

Cardiac Rhythm Management

SEARCH [cancel](#)

**4** Medtronic Facility and Operating Units

Indicate which Medtronic Facilities and Operating Units will be affected by this change.

[Search for Facilities](#)

Medtronic CryoCath LP, Pointe-Claire, Canada REMOVE

**\* Medtronic Affected Facilities**

Please identify impacted operating units (OUs). If you are unsure which OU(s) are affected, please communicate with your Preferred Medtronic Contact(s).

Cardiac Rhythm Management

Cardiac Rhythm and Heart Failure (Inactive)

When searching for facility, start typing on any fields and select from the options that appear. Keep other fields blank and hit search

# PREFERRED MEDTRONIC CONTACT

- Preferred Medtronic contact is an optional field
- Include especially if previously submitting change requests manually, direct to a contact
- Preferred contact will be notified of the submission

## SUPPLIER CHANGE REQUEST

[My Requests](#) [New Request](#) [Account Information](#)

Request 114641 - Sample Change Request

### REQUEST SECTIONS

- ✓ [Change Details](#)
- ✓ [Change Evaluation](#)
- [Medtronic Affected Facilities](#)**
- [Supplier Information](#)
- [Review and Submit](#)

### MEDTRONIC AFFECTED FACILITIES

\* indicates required information

\* **Medtronic Facility and Operating Units**  
Indicate which Medtronic Facilities and Operating Units will be affected by this change.

[Search for Facilities](#)

**Preferred Medtronic Contact(s)**  
If you typically work with a specific Medtronic contact, please provide their name here.

[delete request](#)

< PREVIOUS    NEXT >

### Help

- For portal support, view the [Help Guide](#);
- For information about a specific change request, contact your Medtronic sourcing partner;
- For general assistance email [rs.changeportalhelp@medtronic.com](mailto:rs.changeportalhelp@medtronic.com).

# FAQS FOR CENTRAL TEAM

## 1. As a supplier representative, I need to enter a change request, but I would like to ask questions of the central team. What is the best way to do that?

The Central team is available to you as needed by email. We suggest you enter as much information as possible in your Supplier Change Request and submit, then follow that request up with an email to [RS.changeportalhelp@medtronic.com](mailto:RS.changeportalhelp@medtronic.com) and include your SCR number in the subject line and your additional questions or comments in the body of the email.

## 2. What if I submitted an SCR and I haven't heard anything back?

A system notice is provided when we have received your SCR. A second system notice is provided when the SCR is assigned to a change owner. If you did not receive a system notice, contact [RS.changeportalhelp@medtronic.com](mailto:RS.changeportalhelp@medtronic.com). If an owner is assigned, follow up with the change owner or your preferred Medtronic contact.

## 3. What is the central team able to help with?

The central team will review and amplify entries submitted from suppliers via the Change Request Portal. Key areas they will validate include assessing part numbers identified for any additional corresponding part numbers and directing the change request to all Medtronic teams who need to assess the change.

## 4. I meant to add an attachment but forgot. What should I do?

If you realized the attachment was not included immediately after sending, you may email [RS.changeportalhelp@medtronic.com](mailto:RS.changeportalhelp@medtronic.com). Use subject: Forgot Attachment – SCR No. XXXXXX. This will help the central team to identify the missing attachment. It is possible central team will disposition the SCR for "More Information Requested" and you will be able to attach it and submit again. Central team may also contact you directly when noticing a missing attachment to obtain it and attach.

## 5. I'm having issues with the Supplier Change Request Portal that I think are technical issues. Should I contact Change Portal Help team?

Yes, Change Portal Help team is your first line of support for using the portal. Please send an email to [RS.changeportalhelp@medtronic.com](mailto:RS.changeportalhelp@medtronic.com). If needed, central team will refer your issue on to higher level support including Medtronic IT support.

## 6. How will central team contact me?

Central team may email you, call you with information submitted to a specific supplier change request or return a change request back to you via the portal.

## 7. Will I be kept informed about how review is going at Medtronic?

You may review your portal request to check its status. Each Medtronic facility will update the change request in the portal. If some facilities have completed their review, but others are still pending, your Medtronic contact may be able to get more information for you.

# MEDTRONIC PROCESSING OF CHANGE

# MEDTRONIC INTERNAL PROCESSING



\* Requested Date of Implementation  
Provide your proposed implementation date for the change.

Impact to Production  
If this change is not implemented, will it impact your ability to fulfill orders?

No  Yes

Date of Impact

- Central team validates information and submits to Change Administrator
- Change Administrator assigns request to Change Owner
- Owner reviews request and identifies review required based on complexity
  - Review resources are assigned
  - Review may be required by up to 9 Medtronic functional teams across multiple facilities
- Implementation plan devised
- Change implemented

# FDA CLASSIFICATION OF MEDICAL DEVICES

- FDA classifications and examples:
  - **Class I** - Examination gloves, wheel chair, tongue depressor
  - **Class II** - Needles, guide catheters, insertable loop recorder
  - **Class III** - Heart valves, ICDs, IPGs, infusion pump
- Device classification depends on the ***intended use*** of the device and also upon ***indications for use***.
- Classification is risk based, that is, the risk the device poses to the patient and/or the user is a major factor in the class it is assigned. Class I includes devices with the lowest risk and Class III includes those with the greatest risk.

The class to which a device is assigned determines, among other things, the type of premarketing submission/application required for FDA clearance to market.

- For Class I or II devices, typically a 510k will be required for marketing.
- For Class III devices, a premarket approval application (PMA) will typically be required for marketing.

**Reference:**

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/>

# REGULATORY NOTIFICATION

## Types of FDA (US) submissions:

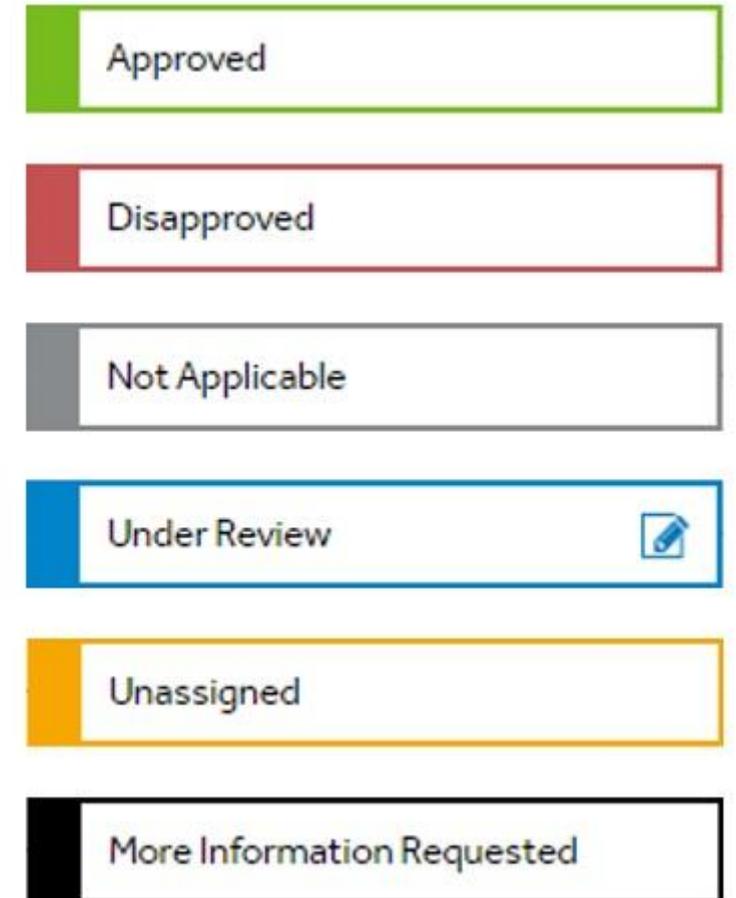
- Document to File
  - Change may be implemented upon completion of internal Medtronic documents
- Annual Report
  - Change may be implemented upon completion of internal Medtronic documents, but is submitted to FDA in a consolidated yearly report
- 30-day Notice
  - FDA will review within 30 days of receiving submission from Medtronic
- Real Time Review (RTR) PMA/S
  - FDA will review in a live meeting and provide response within 90 days, if not converted to a longer submission
- 180 Day PMA/S
  - FDA will review within 180 days
- 510(k)
  - Timeframe depends on complexity of device
- Pre-Market Approval (PMA)
  - Timeframe depends on complexity of device

Non-US Regulatory body submissions (e.g., Canada, EU, etc.) may also be required

Medtronic Corporate policy allows up to 15 business days for Medtronic Non-US Regulatory specialists to evaluate a change and determine if their geography's Regulatory body requires notification

# DISPOSITION THE CHANGE REQUEST

- Each Facility will provide a final status
- Final Status
  - **Approved** – approved for Operating Units, change may proceed
  - **Disapproved** – disapproved for Operating Units, change cannot move forward for this Operating Units
  - **Not Applicable** – indicates change was not relevant to selected Operating Units
- In Progress Status
  - **Unassigned** – a Change Owner is not assigned yet
  - **Under Review** – default status once assigned to a Change Owner
  - **More Information Requested** – more information is needed about the change



# MORE INFORMATION REQUESTED – PORTAL VIEW

## NOTIFICATION FOR ADDITIONAL INFORMATION

- Medtronic can return an SCR to a supplier to request more information.
- Suppliers will receive email notification when additional information is requested.
- Click ID number for comments returned to supplier
- Note: All activities in the SCR are frozen when the request is under More Information Requested

### SUPPLIER CHANGE REQUEST

My Requests | New Request | Account Information

Filter By:

APPLY FILTER(S) REMOVE FILTER(S)

Request ID:  Title:  Submitted Date: All  Implementation Date: All  Operating Unit: All  Change Request Status: Open  Operating Unit Status: All

Request ID	Title	Submitted Date	Implementation Date	Status
<a href="#">114642</a>	Change Request Sample		2021-Nov-17	More Information Requested

# MORE INFORMATION REQUESTED – EMAIL VIEW

## NOTIFICATION FOR ADDITIONAL INFORMATION

- Medtronic can return an SCR to a supplier to request more information.
- Suppliers will receive email notification when additional information is requested.
- Click ID number for comments returned to supplier

noreply@medtronic.com | RS Testing Room; RS Testing Room; + 9 | 1 | 6/16/2021

Medtronic request for more information about 114558

ChangeRequest\_114558.pdf  
.pdf File

Please see the comments below for requested additional information about this change.

<b>Request Tracking ID:</b>	114558
<b>Request Title:</b>	Reason for Change not COvid 19
<b>Operating Unit:</b>	Aortic and Peripheral Vascular (Inactive)
<b>Facility:</b>	Galway
<b>Medtronic Change Owner:</b>	
<b>Change Status:</b>	More Information Requested
<b>Additional Information Requested:</b>	Expect to see details here about information requested

Once the information is entered into the Supplier Change Request portal, you must submit the request again. Please do not respond to this email with the information.

Medtronic is still in the process of evaluating the change request and this e-mail does not constitute an approval. If you have questions about the current status, please review the change request at the following link <https://wwwp-test.medtronic.com/changerequest> (your system login and password are required to access the link) or contact the change owner identified above.

Thank you for using the **Medtronic Supplier Change Request System**.

For help with this system you may contact [rs.changeportalhelp@medtronic.com](mailto:rs.changeportalhelp@medtronic.com)

# MORE INFORMATION REQUESTED

## UPDATE REQUEST AND RESUBMIT

- Supplier can then access the request in the portal, update the content per the notification comments and resubmit.
- Once all content has been updated, the SCR must be resubmitted to Medtronic for further review and continued disposition.

The screenshot displays the 'SUPPLIER CHANGE REQUEST' portal interface. At the top, there are three tabs: 'My Requests', 'New Request' (which is active), and 'Account Information'. Below the tabs, the page title is 'Request 114452 - SCR Training'. On the left side, there is a 'REQUEST SECTIONS' sidebar with four items: 'Change Details' (checked), 'Change Evaluation' (checked), 'Medtronic Affected Facilities' (checked), and 'Supplier Information' (checked). Below these is a 'Review and Submit' button, which is highlighted with a green border. At the bottom of the sidebar is a 'Review Request' button. The main content area is titled 'CHANGE DETAILS' and contains the following fields:

- A note: *\* indicates required information*
- A required field: **\* Change Title** with the instruction 'Provide a brief title for the change (e.g. Change of raw material supplier, Use As Is disposition request, Planned Deviation request)'. The input field contains 'SCR Training'.
- A section for 'Medtronic Part Number / Rev' with the instruction 'List or attach the Medtronic Part Number(s) affected by this change and current Revision.' and radio buttons for 'List' (selected) and 'Attach'.
- Two rows of input fields for 'Medtronic Part Number' and 'Revision':
  - Row 1: MDT123456, Revision [ ]
  - Row 2: MDT456789, Revision [ ] X
- A '+ Add Another' link at the bottom.

# EXAMPLE NOTIFICATION

 noreply@medtronic.com | RS Testing Room; + 13 | 1 | 6/16/2021

**Request 114581 has been closed by Medtronic**

 ChangeRequest\_114581.pdf  
.pdf File

The following change request has been dispositioned by all affected Operating Units and is now considered closed.

**Request Tracking ID:** 114581  
**Request Title:** Demo for Training

The table below summarizes the disposition of the change request

Operating Unit	Facility	Disposition Status	Disposition Comments	Medtronic Contact
Neuromodulation	MTC - Medtronic Tempe Campus	Disapproved	null	Julie Anne Cabral, <a href="mailto:julianne.a.cabral@medtronic.com">julianne.a.cabral@medtronic.com</a>
Cardiac Rhythm and Heart Failure (Inactive)	Mounds View Campus	Approved		Nick Krasucki, <a href="mailto:nick.a.krasucki@medtronic.com">nick.a.krasucki@medtronic.com</a>
Diabetes	MTC - Medtronic Tempe Campus	Approved	null	Vincent Palivoda, <a href="mailto:vincent.palivoda@medtronic.com">vincent.palivoda@medtronic.com</a>

If you have any question about the disposition state or comments associated with this change, please contact the appropriate Medtronic contact listed above.

This will be the final notification regarding this change.

You can access your change request at the following link using your system login and password: <https://wwwp-test.medtronic.com/changerequest>

Thank you for using the **Medtronic Supplier Change Request System**.

# CONCLUSION & HELP

## REMEMBER:

Submit your request in the Supplier Change Request Portal

[changerequest.medtronic.com](https://changerequest.medtronic.com)



For assistance with the system, please contact your Medtronic Quality partner or the central team at [rs.changeportalhelp@Medtronic.com](mailto:rs.changeportalhelp@Medtronic.com)

**Medtronic**

Further, Together