



CALYX™

Best Practice: Managing Medical Device Kits

CALYX.AI

1 Best Practice Revision History

When Calyx releases a new version of Calyx RIM, they issue Release Notes which explain the new features and updates. Calyx reviews the Release Notes against each Best Practice to determine any impact to the document:

- Impact = Release notes for upgrade change this Best Practice
- No Impact = Release notes for upgrade do not change this Best Practice

When Release Notes impact Best Practice documentation, Calyx recommends that clients review the entire Release Notes for a full understanding of all associated changes.

Software Version	Release/Revision Date	Summary of Change(s) (Refer to Release Notes for Full Description)
7.0	09-Aug-2021	Create BP for Medical Device Convenience & Procedure Kits

2 Contents

- 3 Document Purpose 5
- 4 Scope 5
- 5 Out-of-Scope 5
- 6 Regulatory Data Assessments 5
- 7 Data Administration Activities..... 5
 - 7.1 Product Family Values 5
 - 7.2 Application Category Values 6
 - 7.3 Application Type Values..... 6
 - 7.4 Event Type Values 6
- 8 Create Medical Device Data Management: Best Practice Overview 7
- 9 Data Management: Convenience and Procedure Kit Use Case..... 9
- 10 Data Management: Full MD Kit Tracking 10
 - 10.1 Product Family, Product, Country-Specific Details & Component – Bandage Tape 11
 - 10.1.1 Product Family 11
 - 10.1.2 Product 12
 - 10.1.3 Country-Specific Details 13
 - 10.1.4 Component 14
 - 10.2 Product Family, Product, Country-Specific Details & Component: Bandages..... 15
 - 10.2.1 Bandage Product Family 15
 - 10.2.2 Bandage Product 15
 - 10.2.3 Bandage Country-Specific Details 16
 - 10.2.4 Bandage Component 16
 - 10.3 Product Family, Product, Country-Specific Details & Component – Gauze Pads..... 17
 - 10.3.1 Gauze Pad Product Family 17
 - 10.3.2 Gauze Pad Product 17
 - 10.3.3 Gauze Pad Country-Specific Details 18
 - 10.3.4 Gauze Pad Component 18
 - 10.4 Application, Event, Sequence & Registration View 19
 - 10.4.1 Application 19
 - 10.4.2 Event 20
 - 10.4.3 Sequence 21
 - 10.4.4 Product Registration 22

11 Optional Guidelines for Product Detail Set Tracking 23

11.1 Master Kit View PDS – Kit View 24

11.2 Master Kit View PDS – Product 1 View..... 24

11.3 Master Kit View PDS – Accessory View 25

11.4 Product 2 – PDS View 25

11.5 Product 3 – PDS View 26

12 Data Management: Registration Tracking Only 27

12.1 Product Family 28

12.2 Product 29

12.3 Application..... 29

12.4 Event 30

12.5 Sequence 30

12.6 Registration 31

3 Document Purpose

The purpose of this document is to provide a Best Practice for managing Medical Device Convenience and Procedure Kit data in Calyx RIM.

4 Scope

Creating Medical Device Product Families, Products, Applications, Events, Sequences and Registrations in the Registrations Component of Calyx RIM. The Best Practice also contains optional recommendations for clients who wish to track packaging, manufacturing and other product details in the Product Detail Set.

To answer questions about Med Device regulatory definitions, please see the Calyx Medical Device Regulatory Overview.

5 Out-of-Scope

Because of the volume of Kit items, it is understood that RIM Product data may be created or updated through integrations with other systems or worksheets. This Best Practice does not address the integration process, which can be discussed with the Calyx Technical Consulting group.

6 Regulatory Data Assessments

1. Determine which Kit items are Products or Accessories [packaging].
2. As general rule, if the client does not own a Kit product, it is an Accessory. (See Calyx Medical Device Regulatory Overview).
3. In RIM 7.0, Kits and their items may be represented in the Application entity.
4. Calyx recommends individual Product Families for each marketed Medical Device Type, but recognizes that existing clients may have one Product Family for all marketed Medical Device Kit Products.

7 Data Administration Activities

7.1 Product Family Values

Depending on your tracking practices, create one or both of the following Product Families:

- **Full Kit Tracking:** Create a new Product Family for each marketed Medical Device, i.e., Bandage,
- **Registration-Only Tracking:** Create one Product Family, *Medical Device Kits*

7.2 Application Category Values

Create the following Medical Device Application Categories for Global Project Planning:

- 510(k) – Abbreviated
- 510(k) – Traditional
- 510(k) – Special
- Technical File
- Convenience Kit
- Procedure Kit

7.3 Application Type Values

Create the following Application Types:

- 510(k) – Abbreviated
- 510(k) – Traditional
- 510(k) – Special
- Device Exempt from Pre-Market Submissions
- Technical File

7.4 Event Type Values

Create the following Event Types:

- Device Design Change
- Device Labeling Change
- Device Manufacturing Change
- Device Sterilization Change
- Device Label Change
- Device Material Change
- Device Supplier Change
- Device Safety and Performance Change
- Device General Change

7.5 Event Type Values

Create Packaging Content and Types for Accessories (see section 11.3)

8 Create Medical Device Data Management: Best Practice Overview

RIM Entity	Kit Products Classified as RIM Products	Kit Products Classified as Accessories	Comment
Product Family	Create an MD Product Family for each Med Device Product in the kit	N/A	
Product (Type)	Create at least one Product for each Medical Device Product Family	N/A	
Country-Specific Details	Create Country-Specific details for device classification		
Component	Create a Component for each GTIN or other company-approved component If desired, identify Manufacturing on the Component	N/A	
Application	<ul style="list-style-type: none"> Create a Kit Application by associating Products from different MD Product Families Registration Type = Product Registration The Application will display under each Product Family Configuration Opportunity: To accommodate the current state PDS, represent Accessories via a configured multi-select. Values must include kit quantity if needed 	N/A	Note: In v7.0, each Application must have at least one Product
Event	<ul style="list-style-type: none"> Create an Event for each new regulatory activity and associate Products in the Kit Configuration Opportunity: Add a multi-select field for Kit Assembly Contractor which maps to PDS > Manufacturer value list 		Leave the Event open if you will create a Product Registration
Sequence	<ul style="list-style-type: none"> Create an Initial Application Sequence 		

RIM Entity	Kit Products Classified as RIM Products	Kit Products Classified as Accessories	Comment
Registration	<ul style="list-style-type: none"> If the device receives regulatory approval from an agency, then create a Product Registration: <ul style="list-style-type: none"> Associate the Registration to the open Event Select the approved Event Products 		

For further Product development in the Product Detail Set, please see the *Optional Guidelines for Product Detail Set Tracking* section.

9 Data Management: Convenience and Procedure Kit Use Case



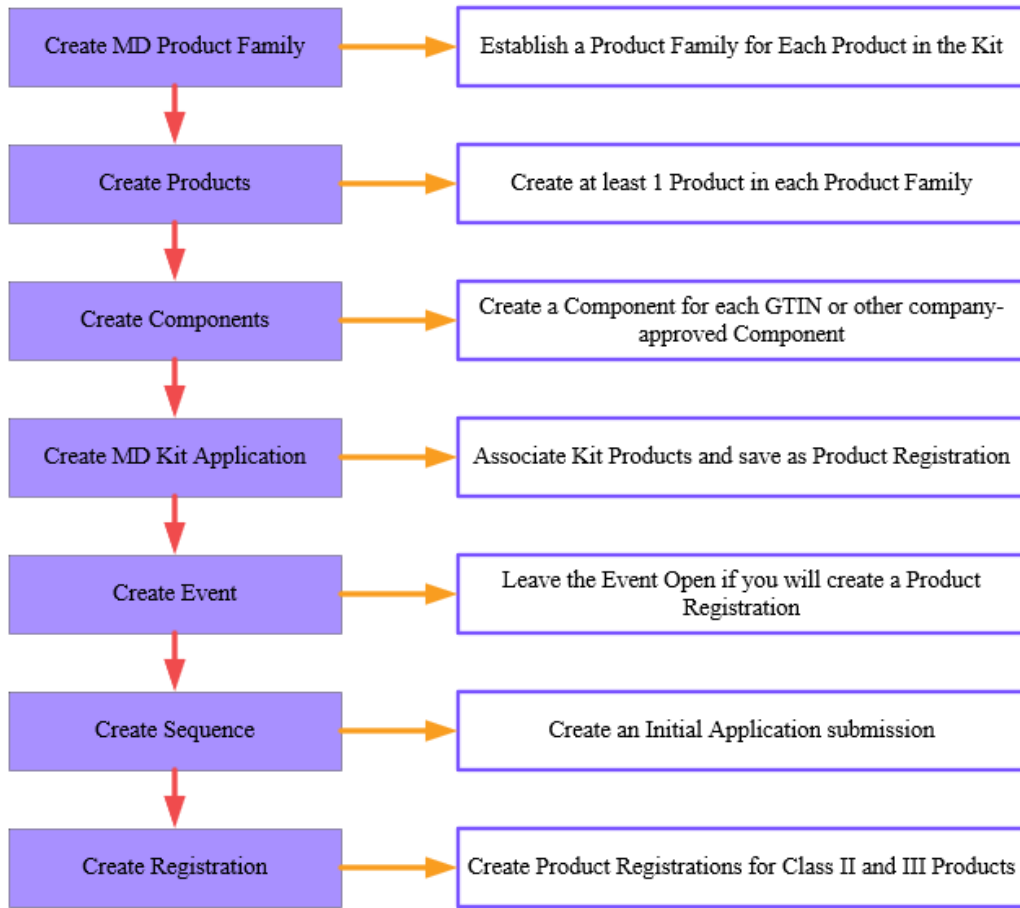
This use case describes a First Aid kit that contains multiple medical devices. The items are packaged together for user convenience and the kit includes:

- Zippered First Aid Kit Bag
- Bandages
- Scissors (3rd party vendor product)
- Roll of Gauze Pads
- Bandage tape

The kit meets the following regulatory requirements:

- It is wrapped or sealed in a single container that is not intended to be unwrapped before use by an end user (Patient, a caregiver, a health practitioner, or a medical technologist)
- The contents should not be substituted, repackaged, sterilized, or processed or modified before being used by an end user
- If desired, the end user may replenish kit contents following use.

10Data Management: Full MD Kit Tracking

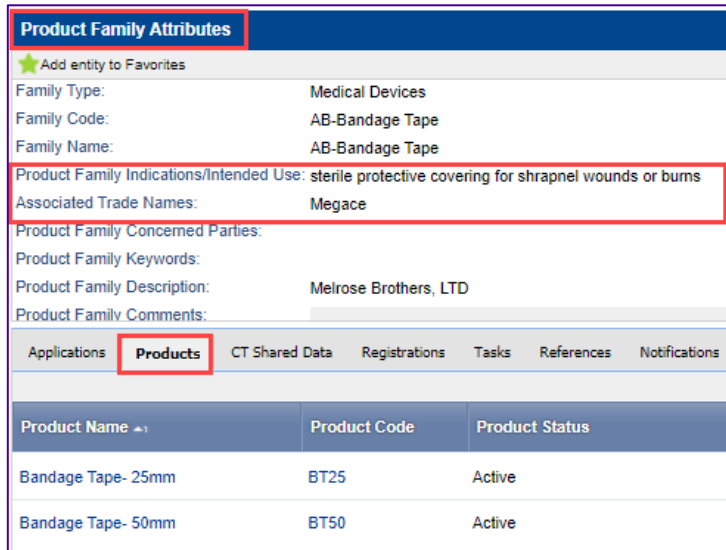


10.1 Product Family, Product, Country-Specific Details & Component – Bandage Tape

10.1.1 Product Family

Screens	Complete the following Fields:
Product Family	<ul style="list-style-type: none"> Family Type Family Name Indication Intended Use: Optional – only PDS is in use Trade Name: Optional – only PDS is in use Description: Name of company that manufactures and registers products

10.1.1.1 Bandage Tape Product Family



Product Family Attributes

★ Add entity to Favorites

Family Type: Medical Devices
 Family Code: AB-Bandage Tape
 Family Name: AB-Bandage Tape
 Product Family Indications/Intended Use: sterile protective covering for shrapnel wounds or burns
 Associated Trade Names: Megace

Product Family Concerned Parties:
 Product Family Keywords:
 Product Family Description: Melrose Brothers, LTD
 Product Family Comments:

Applications **Products** CT Shared Data Registrations Tasks References Notifications

Product Name	Product Code	Product Status
Bandage Tape- 25mm	BT25	Active
Bandage Tape- 50mm	BT50	Active

Note: Accessories that belong to a 3rd party vendor are not represented as RIM Products.

10.1.2 Product

Screens	Fields
Product	<ul style="list-style-type: none"> ● Product Name ● Product Code: Tracking No from Enterprise Resource Planning System (EFP, e.g., SAP) ● Indication/Intended Use: Displays approved PDS IIUs ● FDA Product Code: U.S. Only ● Conformity Assessment Path: EU Only ● Declaration of Conformity Completed: EU Only ● Product Manufacturing Location: Global ● EC Cert: EU Only ● CE Marked: EU Only ● CE Date: EU Only ● Global Medical Device Nomenclatures (GMDN) Code: US Only ● Product Sterilization: Global ● Product Shelf Life: Global

10.1.2.1 Bandage Tape Product

Product Attributes

★ Add entity to Favorites | Product Family: AB-Bandage Tape → Product: Bandage Tape- 25mm

Family Type: Medical Devices

Family Code: AB-Bandage Tape

Family Name: AB-Bandage Tape

Product Name: Bandage Tape- 25mm

Product Code: BT25

Indications/Intended Use:

Product Status: Active

Product Status Date: 14-Jul-2021

Reason for Termination/Withdrawal:

FDA Product Code: DWL ←

Conformity Assessment Path:

Declaration of Conformity Completed: No

Product Manufacturing Location: Braun Medical Inc. ←

EC Cert:

Applicable Standards:

Equipment Type:

Summary of Technical Documentation (STED):

Tech File Number:

CE Marked: No

CE Date:

Global Harmonization Task Force Class (GHTF):

Global Medical Device Nomenclature (GMDN) Code: 652 - Skin-cover adhesive strip, non-antimicrob ←

UMDNS Code:

Product Sterilization: Ethylene Oxide Sterilization ←

Product Shelf Life: 5 years

Components

Product Detail Sets
Product Detail Set Templates
Applications
Registrations
Count

Component Type	Component Name
Med Device	Bandage Tape- 25mm

10.1.3 Country-Specific Details

Screens	Complete the following Fields:
Country-Specific Detail	<ul style="list-style-type: none"> Country Specific Detail Type Country Country Specific Detail Value (Device Class)

10.1.3.1 Bandage Tape Country-Specific Details

Country Specific Detail Attributes

★ Add entity to Favorites | Product Family: AB-Bandage Tape » Product: Bandage Tape- 25mm » Country Specific Detail: Class I

Family Type: Medical Devices

Family Code: AB-Bandage Tape

Family Name: AB-Bandage Tape

Product Name: Bandage Tape- 25mm BT25

Country Specific Detail Type: 2.FDA Device Class ←

Country: United States ←

Country Specific Detail Value: Class I ←

Country Specific Detail Comments:

10.1.4 Component

Screens	Fields
Component	<ul style="list-style-type: none"> • Component Type • Component Name • Component Manufacturing Location • Component Sterilization • Device Usage • Model Number • Sterility Indicator • Sterilization Requirement Indicator • Device Type

10.1.4.1 Bandage Tape Component

Component Attributes

★ Add entity to Favorites | Product Family: AB-Bandage Tape » Product: Bandage Tape- 25mm » Component: Ba

Family Type: Medical Devices

Family Code: AB-Bandage Tape

Family Name: AB-Bandage Tape

Product Name: Bandage Tape- 25mm BT25

Component Type: Med Device

Component Name: Bandage Tape- 25mm

Component Manufacturing Location: Jiangsu Micsafe Medical Tehcnology Co.,LTD., Vygon Corporation

Component Sterilization: Ethylene Oxide Sterilization

Allergenicity Indicator:

Device Usage: For single use only

Model Number: BT25MM

Sterility Indicator: Device is packaged as Sterile - Yes

Sterilization Requirement Indicator: Does Not Require Sterilization Prior to Use

Device type: Adhesive Tape

10.2 Product Family, Product, Country-Specific Details & Component: Bandages

10.2.1 Bandage Product Family

Product Family Attributes

★ Add entity to Favorites

Family Type: Medical Devices
 Family Code: AB-Bandages
 Family Name: AB-Bandages

Product Family Indications/Intended Use: Sterile protective covering for small cuts and bruises

Associated Trade Names: Calyxate

Product Family Concerned Parties:
 Product Family Keywords:
 Product Family Description: Caleb-Johnson
 Product Family Comments:

Applications **Products** CT Shared Data Registrations Tasks References Notifications

Product Name ↕	Product Code	Product Status
Bandages - 60 adhesive .75in x 3 in	B60A	Active
Bandages - 60 adhesive 1in x 3 in	B60AD	Active

10.2.2 Bandage Product

Product Attributes

★ Add entity to Favorites | Product Family: AB-Bandages » Product: Bandages - 60 adhesi...

Family Type: Medical Devices
 Family Code: AB-Bandages
 Family Name: AB-Bandages

Product Name: Bandages - 60 adhesive .75in x 3 in
 Product Code: B60A

Indications/Intended Use:
 Product Status: Active
 Product Status Date: 14-Jul-2021
 Reason for Termination/Withdrawal:

FDA Product Code: KGX ←

Conformity Assessment Path:
 Declaration of Conformity Completed: No
 Product Manufacturing Location: Sol-Millennium Medical Inc. ←

EC Cert:
 Applicable Standards:
 Equipment Type:
 Summary of Technical Documentation (STED):
 Tech File Number:
 CE Marked: No
 CE Date:
 Global Harmonization Task Force Class (GHTF):
 Global Medical Device Nomenclature (GMDN) Code: 840 - Compression bandagi ←

UMDNS Code:
 Product Sterilization: Radiation Sterilization ←
 Product Shelf Life: None

Components Product Detail Sets Product Detail Set Templates Applications Regist

Component Type ↕	Component Name
Med Device	Bandages - 60 adhesive .75in x 3 in

10.2.3 Bandage Country-Specific Details

Country Specific Detail Attributes	
★ Add entity to Favorites Product Family: AB-Bandages » Product: Bandages - 60 adhes	
Family Type:	Medical Devices
Family Code:	AB-Bandages
Family Name:	AB-Bandages
Product Name:	Bandages - 60 adhesive .75in x 3 in B60A
Country Specific Detail Type:	2.FDA Device Class ←
Country:	United States ←
Country Specific Detail Value:	Class I ←
Country Specific Detail Comments:	

10.2.4 Bandage Component

Component Attributes	
★ Add entity to Favorites Product Family: AB-Bandages » Product: Bandages - 60 adhes	
Family Type:	Medical Devices
Family Code:	AB-Bandages
Family Name:	AB-Bandages
Product Name:	Bandages - 60 adhesive .75in x 3 in B60A
Component Type:	Med Device
Component Name:	Bandages - 60 adhesive .75in x 3 in
Component Manufacturing Location:	Biotronix Healthcare Industries, Inc.
Component Sterilization:	Radiation Sterilization
Allergenicity Indicator:	
Device Usage:	For single use only
Model Number:	60B
Sterility Indicator:	Device is packaged as Sterile - Yes
Sterilization Requirement Indicator:	Does Not Require Sterilization Prior to Use
Device Type:	Bandage

10.3 Product Family, Product, Country-Specific Details & Component – Gauze Pads

10.3.1 Gauze Pad Product Family

Product Family Attributes

★ Add entity to Favorites

Family Type: Medical Devices
 Family Code: AB-Gauze Pads
 Family Name: AB-Gauze Pads

Product Family Indications/Intended Use: Sterile protective covering for third degree wounds or burns

Associated Trade Names: Ventolin

Product Family Concerned Parties:
 Product Family Keywords:
 Product Family Description:
 Product Family Comments: <Lisa.Lombardo> Jul 29, 2021 5:32:45 PM Titus LTD (modify) (delete)

Applications **Products** CT Shared Data Registrations Tasks References Notifications Active Ingre

Product Name	Product Code	Product Status
Sterile Gauze Pads, 2" x 2" 4 ct	SGP224	Active
Sterile Gauze Pads, 3" x 3" 4 ct	SGP334	Active

10.3.2 Gauze Pad Product

Product Attributes

★ Add entity to Favorites | Product Family: AB-Gauze Pads > Product: Sterile Gauze Pads, ...

Family Name: AB-Gauze Pads
 Product Name: Sterile Gauze Pads, 2" x 2" 4 ct
 Product Code: SGP224

Indications/Intended Use:
 Product Status: Active
 Product Status Date: 14-Jul-2021
 Reason for Termination/Withdrawal:
 FDA Product Code: JKA

Conformity Assessment Path:
 Declaration of Conformity Completed: No
 Product Manufacturing Location: Vygon Corporation

EC Cert:
 Applicable Standards:
 Equipment Type:
 Summary of Technical Documentation (STED):
 Tech File Number:
 CE Marked: No
 CE Date:
 Global Harmonization Task Force Class (GHTF):
 Global Medical Device Nomenclature (GMDN) Code: 67054 - Compression/pressure sock/stocking, sin

UMDNS Code:
 Product Sterilization: Ethylene Oxide Sterilization
 Product Shelf Life: None

Components Product Detail Sets Product Detail Set Templates Applications Registrations Country Spec

Component Type	Component Name
Med Device	Sterile Gauze Pads, 2" x 2" 4ct

10.3.3 Gauze Pad Country-Specific Details

Country Specific Detail Attributes	
★ Add entity to Favorites Product Family: AB-Gauze Pads » Product: Sterile Gauze Pads, ...	
Family Type:	Medical Devices
Family Code:	AB-Gauze Pads
Family Name:	AB-Gauze Pads
Product Name:	Sterile Gauze Pads, 2" x 2" 4 ct SGP224
Country Specific Detail Type:	2.FDA Device Class ←
Country:	United States ←
Country Specific Detail Value:	Class I ←
Country Specific Detail Comments:	

10.3.4 Gauze Pad Component

Component Attributes	
★ Add entity to Favorites Product Family: AB-Gauze Pads » Product: Sterile Gauze Pads, ...	
Family Type:	Medical Devices
Family Code:	AB-Gauze Pads
Family Name:	AB-Gauze Pads
Product Name:	Sterile Gauze Pads, 2" x 2" 4 ct SGP224
Component Type:	Med Device
Component Name:	Sterile Gauze Pads, 2" x 2" 4ct
Component Manufacturing Location:	Braun Medical Inc.
Component Sterilization:	Ethylene Oxide Sterilization
Allergenicity Indicator:	
Device Usage:	For single use only
Model Number:	224SGP
Sterility Indicator:	Device is packaged as Sterile - Yes
Sterilization Requirement Indicator:	Does Not Require Sterilization Prior to Use
Device Type:	Gauze Pads
Device Manufacturer:	

10.4 Application, Event, Sequence & Registration View

10.4.1 Application

Screens	Complete the following Fields:
Application	<ul style="list-style-type: none"> • Reviewing Country • Application Code • Application Name • Application Type • Procedure Type • Registration Type: Product Registration for MD Product • Product(s) • Application Owner • Legal Status • Application Status • Application Status Date

10.4.1.1 First Aid Kit Application

Application Attributes

★ Add entity to Favorites

Reviewing Country: United States

Region(s): Regulatory Region - United States

Applicant ID: smoke

Internal Code:

Application Code: Exempt

Application Name: First Aid Kit - Calyx Basic

Application Type: Device Exempt from Premarket Submission

Procedure Type: National US

Procedure Start Date:

Procedure End Date:

Procedure Identifier:

Registration Type: Product Registration

Planned Submission Date:

Actual Submission Date:

Planned Approval Date:

Actual Approval Date: 19-Jul-2021

Related Applications:

Legal Status: Over the Counter

Legal Basis:

Application Owner: Camco Inc

Orphan Drug: Undefined

Orphan Drug Last Updated: 14-Jul-2021

Dossier Language:

Next Renewal Date:

Annual Report Date:

Clinical Trials #:

Application Status: Active

Products
Events
Sequences
Countries
Registrations
Product Detail Sets
Tasks
Activities
Workflows
References
Notifications

Product Name ↕	Family Type	Family Name	Family Code
Bandage Tape- 25mm	Medical Devices	AB-Bandage Tape	AB-Bandage Tape
Bandages - 60 adhesive .75in x 3 in	Medical Devices	AB-Bandages	AB-Bandages
Sterile Gauze Pads, 2" x 2" 4 ct	Medical Devices	AB-Gauze Pads	AB-Gauze Pads

10.4.2 Event

Screens	Complete the following Fields:
Event	<ul style="list-style-type: none"> • Event Code: Client-defined • Event Name • Action Type • Event Type • Secondary Event Type • Timeline/Event Plan: Client-defined • Product(s) • Variation Number • PSUR Flag: PMD Product only • PSUR Report Code: PMD Product only • Reportable in PSUR: PMD Product Only

10.4.2.1 First Aid Kit Event

Event Attributes

★ Remove from Favorites | Application: First Aid Kit - Caly... » Event: First Aid Kit 123 - ...

Application Code:	Exempt
Application Name:	First Aid Kit - Calyx Basic
Application Internal Code:	
Project Name:	
Closed:	No
Event Code:	KitP0001
Event Name:	First Aid Kit 123 - Initial Application
Action Type:	Notification Only
Event Type:	New Application
Secondary Event Type:	Full Filing

Countries Country Schedules Products Sequences Change Details **Product Detail Sets**

Product Detail Set Name ▲ ₁	Pr
Bandage Tape- 25mm	
Bandages - 60 adhesive .75in x 3 in	
Sterile Gauze Pads, 2" x 2" 4 ct - Master Kit View	

10.4.3 Sequence

Screens	Complete the following Fields:
Sequence (Submission)	<ul style="list-style-type: none"> • Sequence Code • Sequence Name • Sequence Status • Sequence Status Date • Filing Type <p>Event</p>

10.4.3.1 First Aid Kit Sequence

View Sequence

★ Add entity to Favorites | Application: First Aid Kit - Caly... » Sequence: 0000 Initial Kit 123...

Application Code: Exempt

Application Name: First Aid Kit - Calyx Basic

Included In Grouped Submission:

Closed: No

Sequence Code: P0000

Sequence Name: 0000 Initial Kit 123 Application

Sequence Status: Planned

Sequence Status Date: 30-Jul-2021

Reason for Termination/Withdrawal:

Filing Type: Original Application

Reviewing Country: United States

Procedure Type: National US

Events: First Aid Kit 123 - Initial Application ←

10.4.4 Product Registration

Products in the First Aid Kit example are Class I Products which require Notification only. No Registration record is necessary.

The example below illustrates a Registration record for a Class III Product. The users created a *Product Registration* (vs a *Package Set Registration*) based on the value selection *Application > Registration Type = Product Registration*.

Screens	Complete the following Fields:
Registration	<ul style="list-style-type: none"> • License Code • Event • Product • MAH/Organization • License Issue Date • Perpetual License • Annual Report Date • Next Renewal Date • Last Renewal Date • Expiration Date/Registration Valid Until • License Status • License Status Date • Currently Marketed • Medicines Regulatory Agency

Registration Attributes

★ Add entity to Favorites | Application: First Aid Kit - Caly... » Registration: P1824199 (Sample PMA...

Application Code:	Exempt
Application Name:	First Aid Kit - Calyx Basic
Country:	United States
License Code:	P1824199 (Sample PMA Class III Product)
Event:	First Aid Kit 123 - Initial Application ←
MAH/Organisation:	MAH 1 Address 1 City 1 BE
MAH/Organisation Last Updated:	30-Jul-2021
License Issue Date:	30-Jul-2021
Perpetual License:	Yes
Annual Report Date:	30-Jul-2022
Next Renewal Date:	
Last Renewal Date:	
Expiration Date/Registration Valid Until:	
License Status:	Active
License Status Date:	30-Jul-2021
Reason for Termination/Withdrawal:	
Currently Marketed:	Yes
In-Licensing:	
Out-Licensing:	
Medicines Regulatory Agency:	Food and Drug Administration
Subject to Additional Monitoring:	Undefined

Products
Tasks
Activities
Workflows
References
Notifications

Product Name ▲1	Product Code	Family Type	Family Name
Bandage Tape- 25mm	BT25	Medical Devices	AB-Bandage Tape
Bandages - 60 adhesive .75in x 3 in	B60A	Medical Devices	AB-Bandages
Sterile Gauze Pads, 2" x 2" 4 ct	SGP224	Medical Devices	AB-Gauze Pads

11 Optional Guidelines for Product Detail Set Tracking

Calyx RIM 7.0 does not provide a solution for tracking packaging information for Accessories and Kits. Clients who wish to track this data must create a PDS for Kit Products, then represent Packaging using the guidelines below.

Screens	You may store data on the following PDS Node:
Product Detail Set	<ul style="list-style-type: none"> • Manufacturing (may also be tracked at Product & Component level) <ul style="list-style-type: none"> ○ Function • Indication/Intended Use • Packaging

Pay particular attention to guidelines, below, for tracking Kits and Packaging in the Product Detail Set.

RIM Entity	Kit Products Classified as RIM Products	Kit Products Classified as Accessories	Comment
Product Detail Set	<ol style="list-style-type: none"> 1. Create 1 PDS for each Product 2. One Product PDS must include the name “Master Kit View” 		Use “Data Carrier Identifier” to track UDI number.
PDS Packaging	<ol style="list-style-type: none"> 1. For the “Master Kit View” PDS: <ul style="list-style-type: none"> • Create a Package Set with a unique name • Track Product Packaging under Package Set > Component > Packaging • Create a uniquely named Kit under Package Set > Packaging <p>For all other Kit Products:</p> <ol style="list-style-type: none"> 1. Create a Package Set using the unique name 2. Track Product Packaging under Package Set > Component > Packaging 	<p>From the “Master Kit View” PDS:</p> <ol style="list-style-type: none"> 1. Track Accessories under Package Set > Packaging <ul style="list-style-type: none"> - UDI data for EU and US is at the Packaging level - Kit gets a UDI - Kit Products get a UDI 	Use “Data Carrier Identifier” to track UDI number.

11.1 Master Kit View PDS – Kit View

The screenshot displays the Master Kit View PDS interface. On the left, a tree view shows the hierarchy of the kit, with 'Sterile Gauze Pads, 2" x 2" 4ct - Master Kit View' selected. The right pane, titled 'Package Detail Attributes', lists various attributes. The 'Container Material' attribute is highlighted with a red box and set to 'Canvas'.

Package Detail Attributes	
Family Code :	AB-Gauze Pads
Family Name :	AB-Gauze Pads
Application Code :	First Aid Kit - Calyx Basic
Application Name :	First Aid Kit - Calyx Basic
Product Name :	Sterile Gauze Pads, 2" x 2" 4 ct
Product Detail Set Name :	Sterile Gauze Pads, 2" x 2" 4 ct - Master Kit View
Packaging Category :	Primary
Package Type :	Travel First Aid Kit
Packaging Status :	Pending
Packaging Status Date :	27-Jul-2021
Data Carrier Identifier :	00381371172108
Container Material :	Canvas
Container Alternate Material :	
Component Quantity :	
Component Quantity Unit :	
Unit of Presentation :	
OC Status :	Not Applicable

11.2 Master Kit View PDS – Product 1 View

The screenshot displays the Master Kit View PDS interface in Product 1 View. The left pane shows a tree view with 'Sterile Gauze Pads, 2" x 2" 4ct' selected. The right pane, titled 'Package Detail Attributes', lists various attributes. The 'Package Type' attribute is highlighted with a red box and set to 'Plastic Wrapper'.

Package Detail Attributes	
Family Code :	AB-Gauze Pads
Family Name :	AB-Gauze Pads
Application Code :	First Aid Kit - Calyx Basic
Application Name :	First Aid Kit - Calyx Basic
Product Name :	Sterile Gauze Pads, 2" x 2" 4 ct
Product Detail Set Name :	Sterile Gauze Pads, 2" x 2" 4 ct - Master Kit View
Component Name :	Sterile Gauze Pads, 2" x 2" 4ct
Packaging Category :	Primary
Package Type :	Plastic Wrapper
Packaging Status :	Pending
Packaging Status Date :	27-Jul-2021
Data Carrier Identifier :	00381371172116
Container Material :	
Container Alternate Material :	
Component Quantity :	
Component Quantity Unit :	
Unit of Presentation :	
OC Status :	Not Applicable

11.3 Master Kit View PDS – Accessory View

Package Detail Attributes	
Family Code :	AB-Gauze Pads
Family Name :	AB-Gauze Pads
Application Code :	Exempt
Application Name :	First Aid Kit - Calyx Basic
Product Name :	Sterile Gauze Pads, 2" x 2" 4 ct SGP224
Product Detail Set Name :	Sterile Gauze Pads, 2" x 2" 4 ct - Master Kit View
Packaging Category :	3rd Party Vendor
Package Type :	Scissors
Packaging Status :	Pending
Packaging Status Date :	27-Jul-2021
Data Carrier Identifier :	00381371172144
Container Material :	Plastic
Container Alternate Material :	
Component Quantity :	
Component Quantity Unit :	

11.4 Product 2 – PDS View

Package Detail Attributes	
Family Code :	AB-Bandage Tape
Family Name :	AB-Bandage Tape
Application Code :	First Aid Kit - Calyx Basic
Application Name :	First Aid Kit - Calyx Basic
Product Name :	Bandage Tape- 25mm
Product Detail Set Name :	Bandage Tape- 25mm
Component Name :	Bandage Tape- 25mm
Packaging Category :	Primary
Package Type :	Plastic Wrapper
Packaging Status :	Pending
Packaging Status Date :	27-Jul-2021
Data Carrier Identifier :	00381371172132
Container Material :	
Container Alternate Material :	
Component Quantity :	

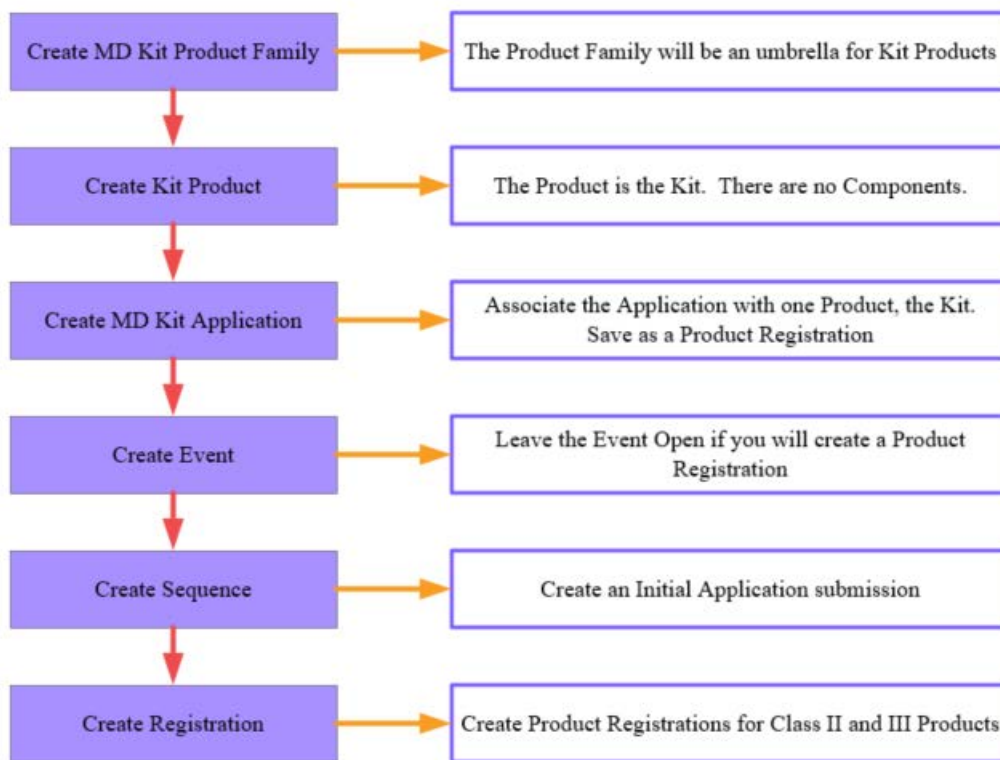
11.5 Product 3 – PDS View

Package Detail Attributes	
Family Code :	AB-Bandages
Family Name :	AB-Bandages
Application Code :	First Aid Kit - Calyx Basic
Application Name :	First Aid Kit - Calyx Basic
Product Name :	Bandages - 60 adhesive .75in x 3 in
Product Detail Set Name :	Bandages - 60 adhesive .75in x 3 in
Component Name :	Bandages - 60 adhesive .75in x 3 in
Packaging Category :	Primary
Package Type :	Box
Packaging Status :	Pending
Packaging Status Date :	19-Jul-2021
Data Carrier Identifier :	00381371172666
Container Material :	Plastic
Container Alternate Material :	
Component Quantity :	

12Data Management: Registration Tracking Only

In some instances, the only data the client wants to track is the MD Kit registration. Clients who use this approach generally track MD data in other systems and only use RIM for basic MD Kit and Catalogue Number (Product) data. In this scenario, there is only one Product, the MD Kit.

Goal	You may complete the following screens:
To track Basic Kit and Catalogue Number	<ul style="list-style-type: none"> • Kit Product Family • Kit Product • Application • Event • Sequence • Registration (Class II and III, as applicable)



12.1 Product Family


Create a Medical Device Kit Product Family to house Kits represented as a single Product.

Product Family Attributes

★ Add entity to Favorites

Family Type: Medical Devices

Family Code: DEVKIT1

Family Name: Medical Device Kits 

Product Family Indications/Intended Use:

Associated Trade Names:

Product Family Concerned Parties:

Product Family Keywords:

Applications **Products** CT Shared Data Registrations Tasks References

Product Name ↕	Product Code	Product St
Calyx - Device Kit 1		Active
First Aid Kit 123		Active

12.2 Product

On the *Product* screen, create a Kit Product without any Components.

Product Attributes	
★ Add entity to Favorites Product Family: Medical Device Kits » Product: First Aid Kit 123	
Family Type:	Medical Devices
Family Code:	DEVKIT1
Family Name:	Medical Device Kits
Product Name:	First Aid Kit 123 ←
Product Code:	
Indications/Intended Use:	
Product Status:	Active
Product Status Date:	09-Aug-2021
Reason for Termination/Withdrawal:	
FDA Product Code:	
Conformity Assessment Path:	
Declaration of Conformity Completed:	No
Product Manufacturing Location:	
EC Cert:	
Applicable Standards:	
<div style="border: 1px solid red; display: inline-block; padding: 2px;">Components</div> Product Detail Sets Product Detail Set Templates Applications Registrat	
Component Type ↕	Component Name ↕
No data found	

12.3 Application

The MD Kit Application will contain only 1 Product, the Kit Product. Make sure the *Registration Type = Product Type*.

Application Attributes			
★ Add entity to Favorites			
Reviewing Country:	United States		
Region(s):	Regulatory Region - United States		
Applicant ID:	smoke		
Internal Code:			
Application Code:	AB-First Aid Kit 123		
Application Name:	AB-First Aid Kit 123 ←		
Application Type:	Device Exempt from Premarket Submission ←		
Procedure Type:	National US ←		
Procedure Start Date:			
<div style="border: 1px solid red; display: inline-block; padding: 2px;">Products</div> Events Sequences Countries Registrations Product Detail Sets Tasks Act			
Product Name ↕	Family Type	Family Name	Family Code
First Aid Kit 123	Medical Devices	Medical Device Kits	DEVKIT1

12.4 Event

Create an Event and associate the Kit Product from the Application. Be sure to leave the Event open so that the Product Registration will detect it.

Event Attributes

Application Code: AB-First Aid Kit 123
 Application Name: AB-First Aid Kit 123
 Application Internal Code:
 Project Name:
 Closed: No
 Event Code:
 Event Name: AB-First Aid Kit 123
 Action Type:

Products

Product Name	Family Name	Event-Product Status	Event-Product Status Date	License Code
<input type="checkbox"/> First Aid Kit 123	Medical Device Kits	Approved	05-Aug-2021	FA123

12.5 Sequence

Create a submission record and associate it to the Event.

View Sequence

Application Code: AB-First Aid Kit 123
 Application Name: AB-First Aid Kit 123
 Included In Grouped Submission:
 Closed: No
 Sequence Code: P0000
 Sequence Name: P0000
 Sequence Status: Planned
 Sequence Status Date: 05-Aug-2021
 Reason for Termination/Withdrawal:
 Filing Type: Original Application
 Reviewing Country: United States
 Procedure Type: National US
 Events: AB-First Aid Kit 123

12.6 Registration

For Class I Kits, no license is necessary. For Class II and III Kits, create a *Product* Registration associated to the MD Kit Product on the Application.

Registration Attributes

★ Add entity to Favorites | Application: AB-First Aid Kit 12... » Registration: FA123

Application Code: AB-First Aid Kit 123

Application Name: AB-First Aid Kit 123

Country: United States

License Code: FA123 ←

Event: AB-First Aid Kit 123 ←

MAH/Organisation: TÜV SÜD America Inc. 5945 Cabot Parkway, Suite 100 Alpharetta ←

MAH/Organisation Last Updated: 05-Aug-2021

License Issue Date: 05-Aug-2021

Perpetual License: Yes

Annual Report Date:

Next Renewal Date:

Last Renewal Date:

Expiration Date/Registration Valid Until:

License Status: Active

License Status Date: 05-Aug-2021

Reason for Termination/Withdrawal:

Currently Marketed: Yes ←

In-Licensing:

Out-Licensing:

Medicines Regulatory Agency: Food and Drug Administration

Subject to Additional Monitoring: Undefined

License Concerned Parties:

Products
Tasks
Activities
Workflows
References
Notifications

Product Name ▲	Family Type	Family Name	Family Code
First Aid Kit 123	Medical Devices	Medical Device Kits	DEVKIT1