

Barcode Requirements

Frequently Asked Questions (FAQs)

(2-August-2015)

Q: Is this announcement and requirement, to include product barcode, limited to devices for layperson only? Or is it for all devices?

A: It is currently required for devices that are intended to be used by Lay Person and Home Use devices only

Q: What levels of packaging does this apply to? Only the unit of sale, or also to the shippers and units of use?

A: It is applicable for the unit of sale as minimum.

Q: What type of barcode format does Saudi FDA require? On our devices, there are multiple barcodes and each contains different information.

A: SFDA barcode preferences are in the following order:

1. If the device comes with UDI Compliant Barcode:

The applicant should enter the information for Static (Fixed) part only; which is known as DI= Device Identifier, as shown in the following example:



(01) 4 5839675 89324 1 (17) 130420 (21) 45443G

**Fixed Device Identifier
(Human Readable Format)**

2. If the device is not tagged with a UDI Compliant Barcode:

The applicant should use the EAN-13/UPC barcode (if available)



3. If the device is not tagged with any of the above 2 Barcode types,

Any other type of Barcode is acceptable

Q: Does SFDA require specific barcode format? Are both Linear OR 2D DataMatrix barcode acceptable?

A: Yes, both are acceptable.

Q: Is there any specific barcode size requirements?

A: No.

Q: How can we provide barcode information for Software only medical devices? Usually there is no barcode on the product labeling

A: If the software is intended to be used by layperson or home use device and no barcode available for this type of products. The applicant can provide a justification for exemption.

Q: Can some products be exempt from the bar code requirements because of their small container / box size or their container material (e.g. foil/ polythene wrap?)

A: All devices for layperson and home use shall be provided with barcodes. If it is not technically possible, the applicant should provide a clear justification for exemption to SFDA for review and give the final decision.

Q: What about the current applications for the Medical Devices which under process now? Is adding Barcode artwork required for it?

A:

- If the first SFDA review after payment was conducted on 7-June-2015 or later the applicant will be required to submit barcode information through the application.
- If the first SFDA review after payment was conducted before 7-June-2015, it is optional to the manufacturer to submit barcode information through the application (Recommended) or to submit the barcode after the application is issued through the new barcode module.

Q: Does this announcement effect immediately?

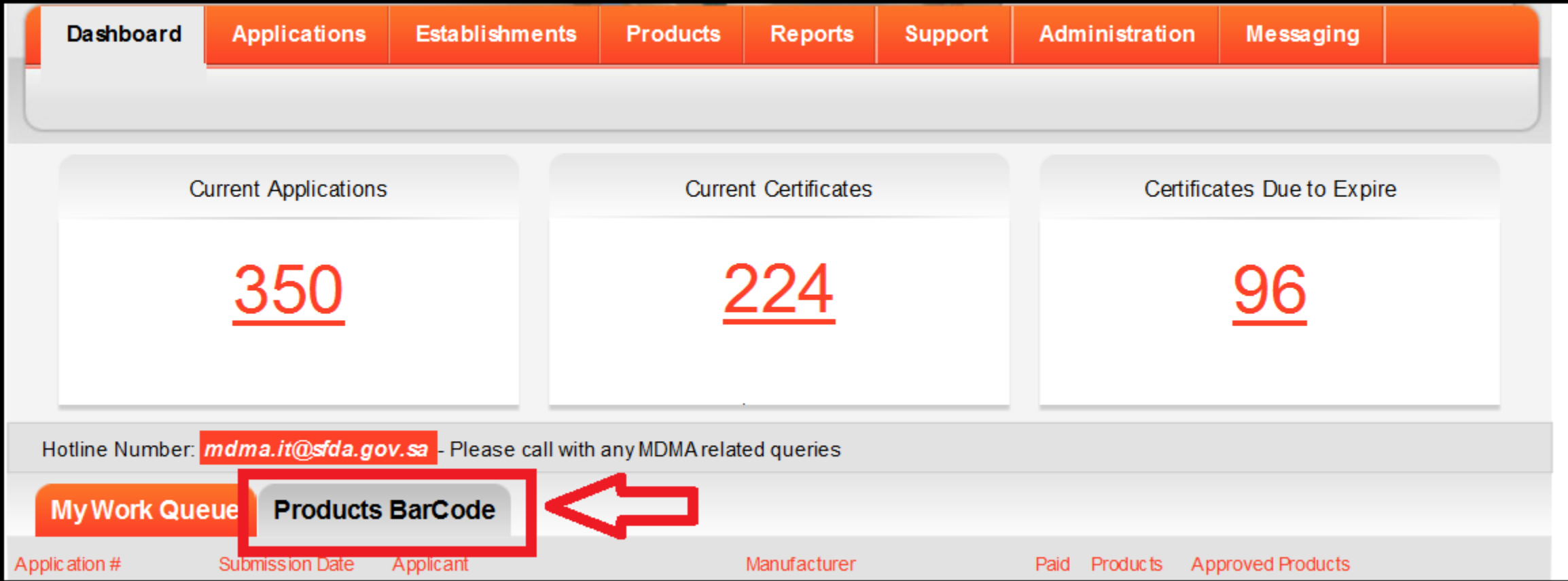
A: Yes, this announcement is effecting immediately.

Q: All our Medical Devices obtained the MDMA license, how update barcode will be in this case? Shall we do it through update authorization?

A: No, no need to use update authorization option. The applicant can submit barcode for products included in an issued authorization through the new Product Barcode module and for free.

Please follow the below steps to use the new Product Barcode module:

Step 1



The screenshot displays the SFDA dashboard with the following elements:

- Navigation Tabs:** Dashboard, Applications, Establishments, Products, Reports, Support, Administration, Messaging.
- Key Metrics:**
 - Current Applications: 350
 - Current Certificates: 224
 - Certificates Due to Expire: 96
- Contact Information:** Hotline Number: mdma.it@sfd.a.gov.sa - Please call with any MDMA related queries
- Navigation Buttons:** My Work Queue, Products BarCode (highlighted with a red box and arrow).
- Table Headers:** Application #, Submission Date, Applicant, Manufacturer, Paid, Products, Approved Products.

Step 2

Current Applications

350

Current Certificates

224

Certificates Due to Expire

96

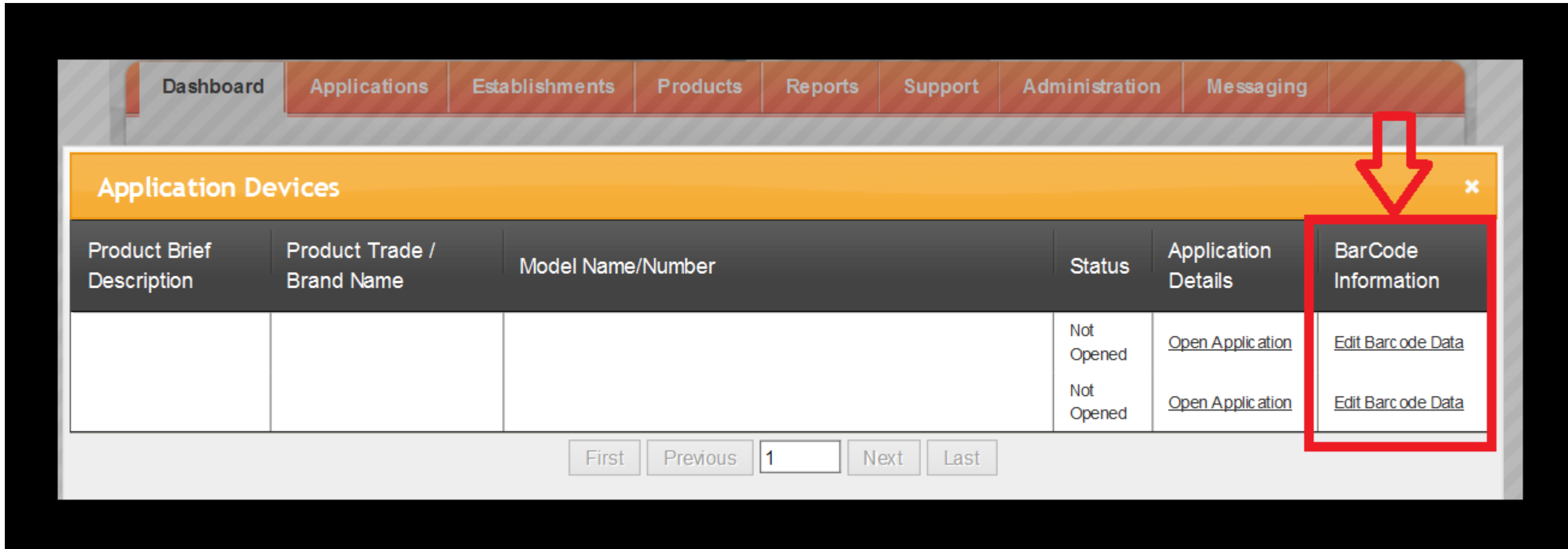
Hotline Number: mdma.it@sfd.a.gov.sa - Please call with any MDMA related queries

My Work Queue

Products BarCode

| Application # | Submission Date | Applicant | Manufacturer | Paid | Products | Approved Products | |
|---------------|-----------------|-----------|--------------|------|----------|-------------------|-------------------------------|
| | | | | Yes | 4 | 0 | Show Products |
| | | | | Yes | 17 | 0 | Show Products |
| | | | | Yes | 4 | 0 | Show Products |
| | | | | Yes | 10 | 0 | Show Products |
| | | | | Yes | 4 | 0 | Show Products |
| | | | | Yes | 2 | 0 | Show Products |
| | | | | Yes | 17 | 0 | Show Products |
| | | | | Yes | 1 | 0 | Show Products |
| | | | | Yes | 2 | 0 | Show Products |
| | | | | Yes | 2 | 0 | Show Products |

Step 3



The screenshot displays a web application interface with a navigation menu at the top containing: Dashboard, Applications, Establishments, Products, Reports, Support, Administration, and Messaging. Below the menu is a window titled "Application Devices" with a close button (x) in the top right corner. A red arrow points from the top right towards the "BarCode Information" column header. The table below has the following structure:

| Product Brief Description | Product Trade / Brand Name | Model Name/Number | Status | Application Details | BarCode Information |
|---------------------------|----------------------------|-------------------|------------|----------------------------------|------------------------------------|
| | | | Not Opened | Open Application | Edit Barc ode Data |
| | | | Not Opened | Open Application | Edit Barc ode Data |

At the bottom of the table, there are pagination controls: First, Previous, 1, Next, Last.

Step 4

Application Devices

Product Brief Description

Barcode Info

2.1.3 Product Trade / Brand Name
[As it appears on the label]
[This field will appear on the MDMA printout]

2.1.1 Product Brief Description
[This field will appear on the MDMA printout]

2.1.10 Provide the label(s) affixed to the device or its wrappers when it is supplied to the KSA. [View Documents](#)

2.1.13 Product Barcode Number (Human Readable Part) that will appear on labeling [List of Barcodes](#)

2.1.14 Indicate if the home use device is designed to be used by Lay Person? If yes, please fill sections (2.1.15 & 2.1.16). If NO, next fields are optional * Yes No

2.1.15 If yes, please provide Device Name in Arabic

2.1.16 If yes, please provide Device Description in Arabic Max: 3000

[Save](#) [Submit](#)

BarCode Information

[Edit Bar code Data](#)

[Edit Bar code Data](#)

