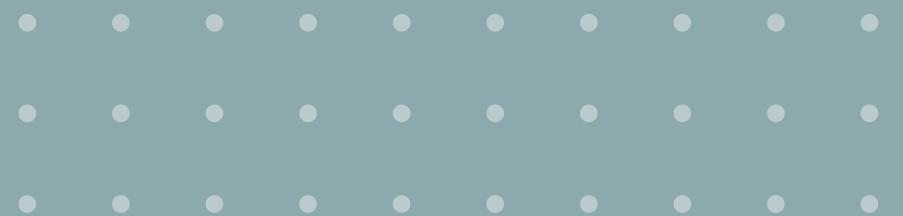




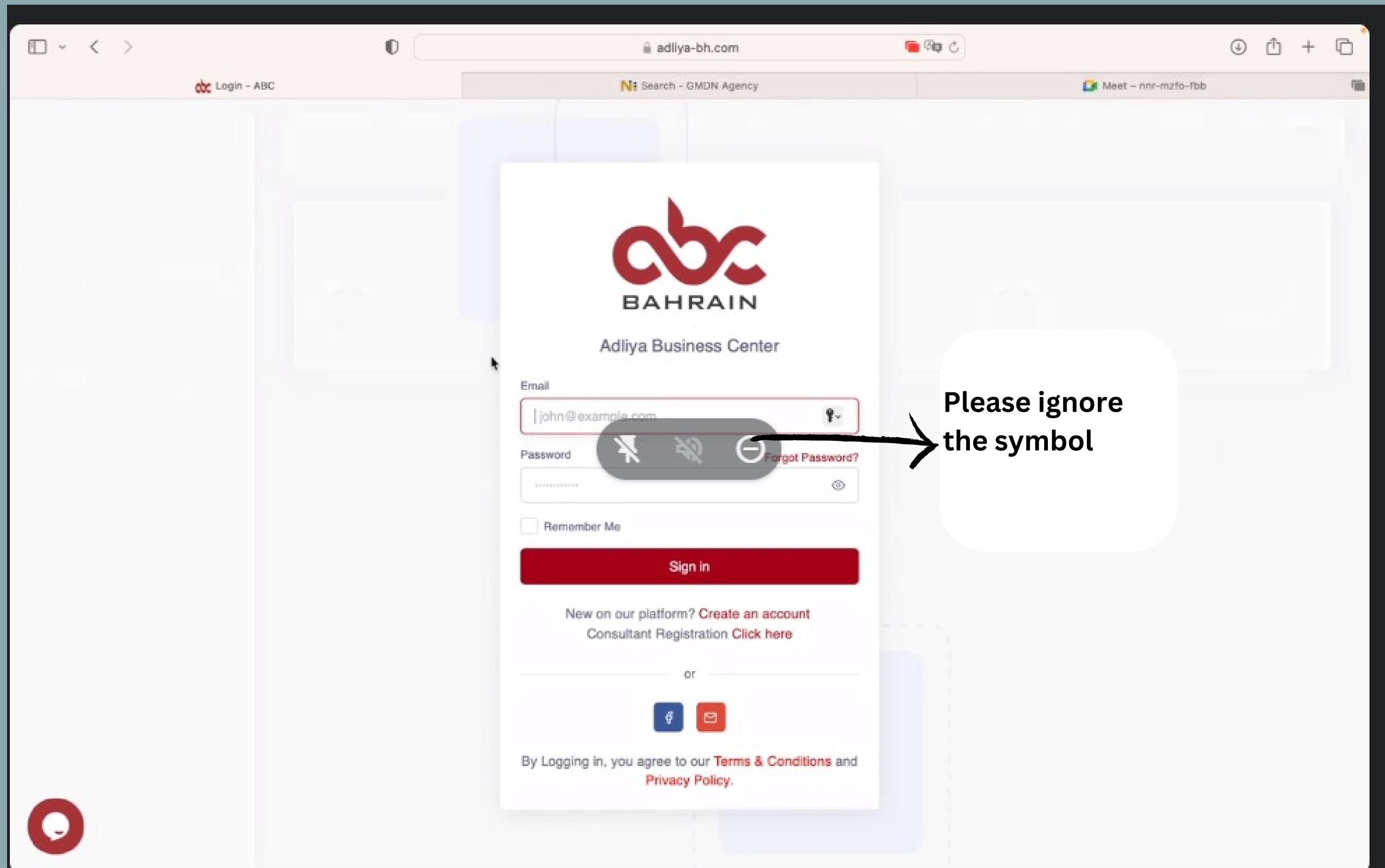
MDR SOFTWARE WIREFRAME - NHRA



STEP 1

The screenshot shows a web browser window with three tabs at the top: "Dashboard - ABC", "Search - GMDN Agency", and "Meet - nrr-mzfo-fbb". The main content area displays the "ABC BAHRAIN" dashboard. On the left, a sidebar titled "APPS & PAGES" lists several options: "Dashboard" (highlighted with a red background), "Registration", "AR Applications", "MDR Applications", "Appointments", and "Customer Support". The main dashboard page has a title "Dashboard" and three main sections: "Registration" (with a pencil icon), "AR Applications" (with a green cube icon), and "MDR Applications" (with a red cube icon).

STEP 2



STEP 3

The screenshot shows a web browser window with three tabs open:

- Dashboard - ABC
- adliya-bh.com
- Meet - nrr-mzfo-fbb

The main content area is the ABC Bahrain dashboard, featuring the following sections:

- Authorized Representative Registration**:
 - (FAST TRACK)
 - (NHRA)
- Medical Device Registration**:
 - (FAST TRACK)
 - (NHRA)
- APPS & PAGES**:
 - Dashboard
 - Registration >
 - AR Applications
 - MDR Applications
 - Appointments
 - Customer Support

A red circular button is visible in the bottom-left corner of the dashboard area.

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STEP 4

The screenshot shows a web browser window with the URL adliya-bh.com. The left sidebar contains a navigation menu with items like Dashboard, Registration, AR Registration, Mdr Registration (which is highlighted in red), AR Applications, MDR Applications, Appointments, and Customer Support. The main content area is titled "Select Type of Registration". It features two tabs: "For New MDR Registration" (selected) and "For Renewal MDR Registration". Under "For New MDR Registration", there are three options: "Medical Device Registration New" (selected with a red dot), "For Variation MDR Registration" (disabled with a grey background), and "Medical Device Registration Variation" (disabled with a grey background). A red "Next" button is at the bottom right. A yellow callout bubble on the right side contains the text: "Please add a fourth option as a Renewal & Variation". A yellow arrow points from the text in the callout to the "For Variation MDR Registration" link.

Please add a fourth option as a Renewal & Variation

STEP 5

The screenshot shows a web browser window with the URL adliya-bh.com. The left sidebar contains a navigation menu with items like 'Dashboard', 'Registration', 'AR Applications', 'MDR Applications', 'Appointments', and 'Customer Support'. The main content area displays a modal dialog titled 'Select Type of Application Replication'. Inside the dialog, there are two radio button options: 'Make New Application For Renewal' and 'Replicate Existing Application For Renewal'. The 'Replicate Existing Application For Renewal' option is selected and highlighted with a cursor. At the bottom right of the dialog, there is a red 'Next' button.

ABC BAHRAIN

Dashboard - ABC

Log in - GMDN Agency

FADI

APPS & PAGES

- Dashboard
- Registration
- AR Applications
- MDR Applications
- Appointments
- Customer Support

Select Type of Application Replication

Make New Application For Renewal Replicate Existing Application For Renewal

Next

STEP 6

The screenshot shows a web-based application for renewing medical device registrations. The top navigation bar includes the URL adliya-bh.com, a search bar, and various browser controls. The main header reads "MDR Application | RENEWAL - ABC". On the left, there's a sidebar titled "APPS & PAGES" with links to "Dashboard", "Registration", "AR Applications", "MDR Applications", "Appointments", and "Customer Support". The main content area is titled "MDR Application | RENEWAL" and features a "Check List" tab which is currently selected. Below the tabs, there's a section for "Terms & Regulations". The main body of the page is titled "Medical Devices Registration Check List" and lists eight points:

1. Medical Devices Registration Application Form. (All sections should be filled).
2. Technical Details such as User manual, Catalogue, and Service Manual.
3. Art Work i.e. Label of the Medical Device. Should include the Name and a device Identification number (catalogue No, reference No, Model No) and legal manufacturer name with address.
(For Similar medical devices bundling group applications with more than 3 medical devices, minimum of 3 artworks should be submitted. For family and IVD bundling group cases where providing all medical device artworks is not feasible, applicants can contact NHRA through email for recommendation).
4. Agreement or Authorization letter issued by the legal manufacturer to the Authorized Representative for the distribution of the applied Medical Device/s in the Kingdom of Bahrain
5. Official Letter issued by the legal manufacturer stating its relationship with the physical manufacturers and regional authorized distributors (invoice issuer) regarding the medical device(s). Full addresses must be stated.
6. Instruction for use (IFU) issued by the Legal Manufacturer with the address matching the artwork. Such as operations/user manual, and leaflet.
7. List of countries the medical device has been marketed in, issued by the Legal manufacturer.
8. If the device has been marketed in Bahrain for a minimum of 3 years, an official letter from the legal manufacturer mentioning Bahrain market field safety notice records for the past 3 years is required.
If the device has not been marketed in Bahrain for a minimum of 3 years, an official letter from the legal manufacturer mentioning worldwide and Bahrain market field safety notice records for the past 3 years is required.
Remark: If there are no field safety notice records, the above points still apply and an official letter from the legal manufacturer needs to be provided stating that there are no field safety notice records related to the devices.

please add a
yes or No Box
option along
with each point

STEP 7

This screenshot shows the 'MDR Application | RENEWAL' page. The 'AR details' tab is selected. It displays fields for 'Company Name' (ABC Bahrain), 'MDR Reference Number' (MDR-Q-ABC-00043), 'Authorized Representative Name', 'Email', 'Mobile', 'AR License Number', 'AR License Attachment', and 'AR License Expiry' (24/06/2023). A note at the top states: 'Please note that all sections must be clearly filled along with checklist documents in order to consider reviewing your application'.

This screenshot shows the 'Details of the Authorized Representative(AR)' page. It includes fields for 'Company Name' (ABC Bahrain), 'MDR Reference Number' (MDR-Q-ABC-00043), 'Authorized Representative Name', 'Email', 'Mobile', 'AR License Number', 'AR License Attachment', 'AR License Expiry' (24/06/2023), 'CR Number', 'CR Attachment', 'CR Expiry', 'CEO Email', 'CEO Name', 'VAT Number (If Applicable)', and 'Address'.

This screenshot shows the 'Address' section of the 'MDR Application | NEW - ABC' page. It contains fields for 'Office/Flat/Shop No.', 'Building No.', 'Road Address', 'Block No.', 'Area', and 'Google Location'. At the bottom right are 'Save & Continue' and 'Next' buttons.

Please add a
address option
after the AR
License expiry
option

STEP 8

The screenshot shows the 'Manufacturer details' tab selected in the top navigation bar. A note at the top states: 'Please note that all sections must be clearly filled along with checklist documents in order to consider reviewing your application'. The 'Manufacturer Details' section contains fields for Legal Manufacturer Name (InnoTERE GmbH), Legal Manufacturer Address (Meißner Straße 191 - 01445 Radebeul), and a file upload field for Letter of Change/Updates. Below this, there are fields for Physical Manufacturer Name (InnoTERE GmbH), Physical Manufacturer Address (Meißner Straße 191 - 01445 Radebeul), Relationship Letter (Choose file (pdf/jpg) 31442281_11062023184013_mdr....), and Relationship License Expiry (31/12/2024).

This screenshot continues the 'Manufacturer Details' section from the previous screen. It shows the continuation of the physical manufacturer information, including the physical manufacturer name (InnoTERE GmbH), physical manufacturer address (Meißner Straße 191 - 01445 Radebeul), relationship letter (Choose file (pdf/jpg) 31442281_11062023184013_mdr....), and relationship license expiry (31/12/2024). A note at the top of this section also requires all sections to be filled with checklist documents.

The screenshot shows the 'Authorization Letter Issuer' section. It includes a radio button for 'Legal Manufacturer' (selected) and 'Other'. Fields for Entity Name (Issuer) (InnoTERE GmbH) and Entity Address (Issuer) (Meißner Straße 191 - 01445 Radebeul) are present. There is also a file upload field for the Authorization letter (Choose file (pdf/jpg)) and a date field for Authorization Letter Expiry (31/12/2024). Navigation buttons at the bottom include 'Save & Continue' and '← Prev'.

STEP 9

MDR Application | RENEWAL - ABC

ABC Bahrain

Medical Device Details

Available placeholder (Click on the sign to Copy)
Trade Mark :™
Registered Sign :®

GMDN Instructions (Click Here)

Device Name: Device Model: HS Code: GMDN Code: Purchase Price (BHD): Purchase Price:

Device Type: In-Vitro Medic
Select Device Type
Non-Active Medical Device
Active Medical Device
In-Vitro Medical Device
Select Risk Classification
Select Manufacturer
Select Legal Manufacturer

Physical Manufacturer: GMDN Link: GMDN Name: GMDN Name:

Use Type: Shelf Life: Market Entry Date: dd-mm-yyyy or N: Purchase Price (BHD): Purchase Price:

Physical Manufacturer: GMDN Link: GMDN Name: GMDN Name:

Devices

SR. NUM	DEVICE NAME	DEVICE MODEL	DEVICE TYPE	HS CODE	GMDN CODE	USE TYPE	RISK CLASSIFICATION	SHELF LIFE
No data available in table								

Show: 10 entries Search: < Previous Next >

Save & Continue

MDR Application | RENEWAL - ABC

ABC Bahrain

Single (Only One Device) Bundle

Available placeholder (Click on the sign to Copy)
Trade Mark :™
Registered Sign :®

GMDN Instructions (Click Here)

Device Name: Device Model: HS Code: GMDN Code: Purchase Price (BHD): Purchase Price:

Device Type: In-Vitro Medic
Select Device Type
Non-Active Medical Device
Active Medical Device
In-Vitro Medical Device
Select Risk Classification
Select Manufacturer
Select Legal Manufacturer

Physical Manufacturer: GMDN Link: GMDN Name: GMDN Name:

Use Type: Shelf Life: Market Entry Date: dd-mm-yyyy or N: Purchase Price (BHD): Purchase Price:

Physical Manufacturer: GMDN Link: GMDN Name: GMDN Name:

Devices

SR. NUM	DEVICE NAME	DEVICE MODEL	DEVICE TYPE	HS CODE	GMDN CODE	USE TYPE	RISK CLASSIFICATION	SHELF LIFE
No data available in table								

Show: 10 entries Search: < Previous Next >

Save & Continue

MDR Application | RENEWAL - ABC

ABC Bahrain

Single (Only One Device) Bundle

Available placeholder (Click on the sign to Copy)
Trade Mark :™
Registered Sign :®

GMDN Instructions (Click Here)

Device Name: Device Model: HS Code: GMDN Code: Purchase Price (BHD): Purchase Price:

Device Type: In-Vitro Medic
Select Device Type
Non-Active Medical Device
Active Medical Device
In-Vitro Medical Device
Select Risk Classification
Select Manufacturer
Select Legal Manufacturer

Physical Manufacturer: GMDN Link: GMDN Name: GMDN Name:

Use Type: Shelf Life: Market Entry Date: dd-mm-yyyy or N: Purchase Price (BHD): Purchase Price:

Physical Manufacturer: GMDN Link: GMDN Name: GMDN Name:

Devices

SR. NUM	DEVICE NAME	DEVICE MODEL	DEVICE TYPE	HS CODE	GMDN CODE	USE TYPE	RISK CLASSIFICATION	SHELF LIFE
No data available in table								

Show: 10 entries Search: < Previous Next >

Save & Continue

MDR Application | RENEWAL - ABC

ABC Bahrain

Medical Device Details

Available placeholder (Click on the sign to Copy)
Trade Mark :™
Registered Sign :®

GMDN Instructions (Click Here)

Device Name: Device Model: HS Code: GMDN Code: Purchase Price (BHD): Purchase Price:

Device Type: In-Vitro Medic
Select Device Type
Non-Active Medical Device
Active Medical Device
In-Vitro Medical Device
Select Risk Classification
Select Manufacturer
Select Legal Manufacturer

Physical Manufacturer: GMDN Link: GMDN Name: GMDN Name:

Use Type: Shelf Life: Market Entry Date: dd-mm-yyyy or N: Purchase Price (BHD): Purchase Price:

Physical Manufacturer: GMDN Link: GMDN Name: GMDN Name:

Devices

SR. NUM	DEVICE NAME	DEVICE MODEL	DEVICE TYPE	HS CODE	GMDN CODE	USE TYPE	RISK CLASSIFICATION	SHELF LIFE
No data available in table								

Show: 10 entries Search: < Previous Next >

Save & Continue

MDR Application | RENEWAL - ABC

ABC Bahrain

Terms & Regulations

Details of the Medical Device

Single (Only One Device) Bundle

Bundling Process

Single Family System

Procedure Pack In-Vitro Diagnostic (IVD)

Devices

Upload Excel File (Max 50 for In-Vitro or Procedure Pack)

Choose file (xlsx,xls) Browse

Download Sample

Physical Manufacturer List

NAME	ID
InnoTERE GmbH	60

Note:
(i) Only sample excel sheet [Filled] will be accepted.
(ii) Fill the Sample with the ID of Legal and Physical manufacturer as per given list.
(iii) Please Leave column Blank if market entry date is unavailable.
(iv) If Physical Manufacturer is multiple for single device use coma separation for the given id's. ex.1,2

please add
GMDN code
should have
only five digits
numeric

STEP 10

The screenshot shows a web browser window with the URL adliya-bh.com. The page title is "MDR Application | RENEWAL - ABC". On the left, there's a sidebar titled "APPS & PAGES" with links to Dashboard, Registration, AR Applications, MDR Applications, Appointments, and Customer Support. The main content area is titled "MDR Application | RENEWAL" and has a sub-section titled "Medical Device Supportive Docs". Below this, there's a heading "Devices Docs" and a note: "Note: Hover over the ⓘ mark to get more details about the document. All the * Documents are required. Please Don't Duplicate the referred devices on a single required document type." There are two sections for "Art Work * ⓘ" and "Instruction For Use * ⓘ", each with a "Choose File" button and a "Select Related Medical Devices" dropdown menu with a green "+" button and a "Select All" checkbox.

Please note, we will share
the checklist.

STEP 11

Please note that all sections must be clearly filled along with checklist documents in order to consider reviewing your application

Medical Device Documents

If not submitted listing form before, Download this file and fill accordingly and send it to medical_devices@nhra.bh and upload screenshot click here to Download!

Medical Device Registration Listing Email Attachment or Screen Capture *

Medical Device Registration Listing Attachment *

Please fill this field

Quality Management System (QMS)

QMS Certificate Number * Notified Body * QMS Certificate * Expiry Date *

Verification Evidence QMS * Confirmation *

The Physical manufacturer is the holder (or one of the sub-facilities) of the quality management Service certificate (Same name and address).

Quality Assurance Certificate (QAC)

QAC Certificate Number * Notified Body * QAC Certificate * Expiry Date *

Verification Evidence QAC * Confirmation *

The Legal manufacturer is the holder (or one of the sub-facilities) of the quality assurance certificate (Same name and address).

EC Design Examination (For Class III and High Risk Medical Devices)

Quality Assurance Certificate (QAC)

QAC Certificate Number * Notified Body * QAC Certificate * Expiry Date *

Verification Evidence QAC * Confirmation *

The Legal manufacturer is the holder (or one of the sub-facilities) of the quality assurance certificate (Same name and address).

EC Design Examination (For Class III and High Risk Medical Devices)

EC Design Certificate Number * Notified Body * EC Design Examination Certificate * Expiry Date *

EC Design Certificate Number * Notified Body * EC Design Examination Certificate * Expiry Date *

Verification Evidence EC Design * Confirmation *

The Legal manufacturer is the holder (or one of the sub-facilities) of the quality assurance certificate (Same name and address).

Save & Continue

← Prev

We like to suggest will
keep the all option in
Previous Medical
Device supportive Doc

STEP 12

This screenshot shows the 'MDR Application | RENEWAL' page. On the left, there's a sidebar with 'ABC BAHRAIN' logo and links for Dashboard, Registration, AR Applications, MDR Applications, Appointments, and Customer Support. The main content area is titled 'MDR Application | RENEWAL' and has tabs for Check List, AR details, Manufacturer details, Medical Device Details, Medical Device Supportive Docs, and Medical Device documents. Below these tabs, 'Terms & Regulations' is selected. It contains a list of 8 points regarding medical device registration guidelines. At the bottom, there's a checkbox for 'Accept Engagement Letter'.

This screenshot shows the 'MDR Application | RENEWAL - ABC' page. The sidebar is identical to the previous one. The main form includes fields for 'Authorized Person Name*', 'Authorized Person Email*', and 'Authorized Person Mobile*'. It also has fields for 'Position*', 'Date*', 'Signature*', and 'Company Stamp*'. Below these, there's a section for 'Other Additional Supportive Documents (If any)' with fields for 'Document Type' and 'Supportive Attachment'. A large yellow callout box with a double quote mark is positioned over this section, containing the instruction: 'please add both Electronic signature & Signature'.

This screenshot shows the final step of the application process. The sidebar and form structure are the same as the previous screenshots. The main form now includes a 'Description' field with placeholder text 'Write a Brief Description' and a 'Save & Continue' button at the bottom right. The copyright notice 'COPYRIGHT © 2022 Adliya Business Center , All rights Reserved' is visible at the bottom of the page.

please add both
Electronic
signature &
Signature

STEP 13

The screenshot shows a web browser window with the URL adliya-bh.com. The page title is "AR Applications - ABC". On the left, there is a sidebar with the "ABC BAHRAIN" logo and links for "APPS & PAGES": Dashboard, Registration, AR Applications, MDR Applications (which is highlighted in red), Appointments, and Customer Support. The main content area displays a table of MDR Applications. The table has columns: APP-NO, COMPANY NAME, AR NAME, STATUS, APP TYPE, SUBMISSION DATE, CURRENT STATUS DATE, and ACTIONS. There are three entries:

APP-NO	COMPANY NAME	AR NAME	STATUS	APP TYPE	SUBMISSION DATE	CURRENT STATUS DATE	ACTIONS
MDR-Q-ABC-00040	InnoTERE GmbH	BLUE ELAF MEDICAL WLL	⌚ Data Incomplete	Renewal	23-Jun-2023	23-Jun-2023	View Application Edit View History
MDR-Q-ABC-00042	BIOSCIENCE GmbH	BLUE ELF MEDICAL WLL	⌚ CE First level screening	Renewal	13-Jun-2023	13-Jun-2023	View Application View History
MDR-Q-ABC-00041	BIOSCIENCE GmbH	BLUE ELF MEDICAL WLL	⌚ CE First level screening	Renewal	13-Jun-2023	13-Jun-2023	View Application View History

At the bottom of the table, it says "Showing 1 to 3 of 3 entries". The footer of the page includes a copyright notice: "COPYRIGHT © 2022 Adliya Business Center , All rights Reserved".