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Kingdom of Bahrain

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Medical Device Registration

17-Aug-2022

Presented by: Eng. Abdullatif Alnaser
Medical Equipment Engineer
NHRA

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Topics to be covered

- What is medical device registration?
- Importance and benefits of medical device registration
- Important points to know before submitting an application
- Medical device registration requirements
- How do NHRA evaluate the medical devices registration application documents?
- Applications review time frame

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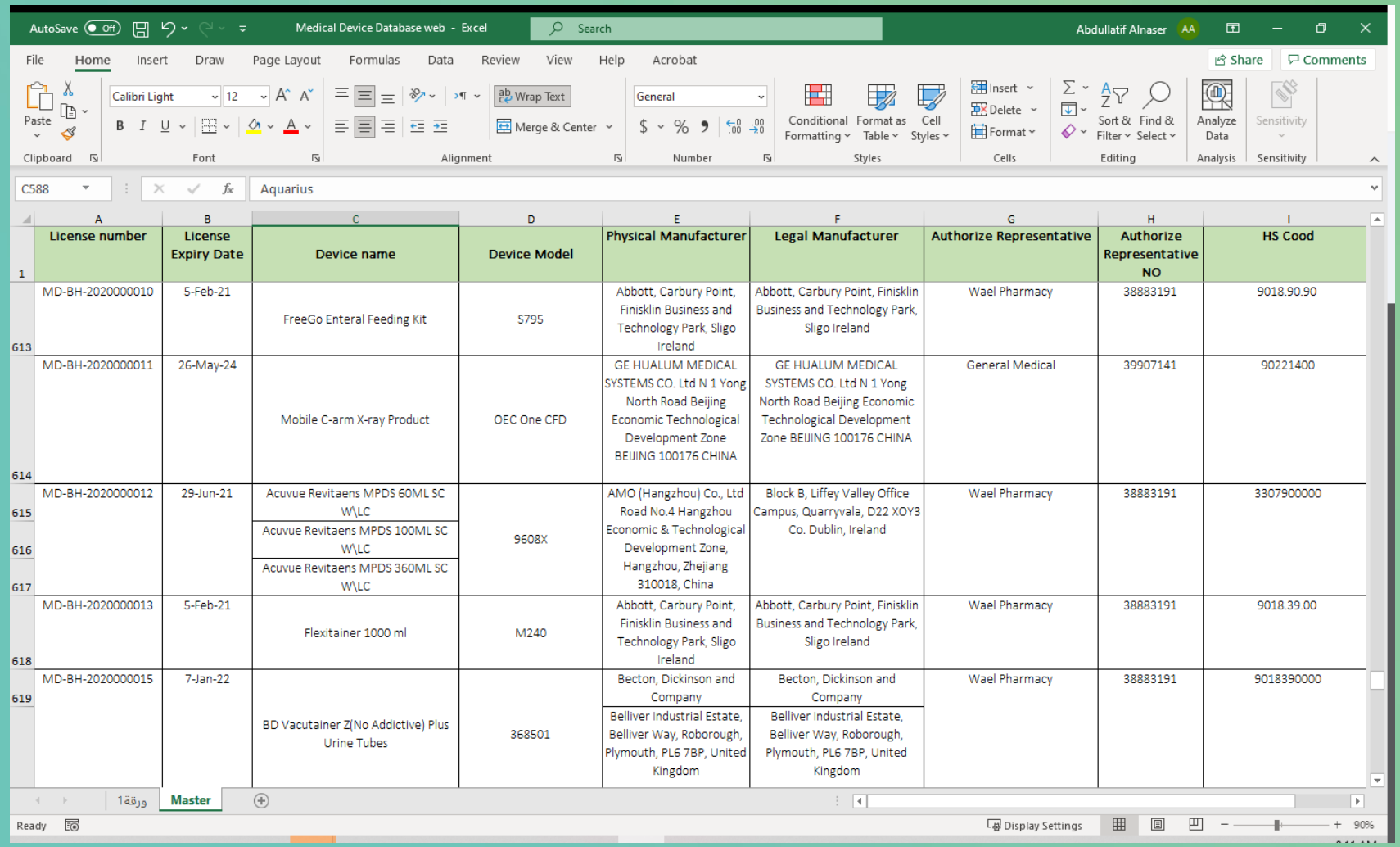
What is medical device registration?

- Medical device registration is basically the process of ensuring the compliance of the medical device quality and safety with international standards.
- By fulfilling requirements that are adapted from worldwide recognized regulatory authorities.

Importance and benefits of medical device registration

- As per Resolution No. (48) of 2020 on Medical Devices and Products' Quality Control, Only registered medical devices can be marketed in Bahrain.
  - Grace period until February 2026.
- Registration enhances the level of traceability of devices in the kingdom and enables the end-user to easily contact the local authorized representatives.
- Registration facilitates the importation process.
- Applicants pay less importation fees for registered devices.
- Healthcare facilities are recommended by NHRA to prioritize purchasing registered medical devices to ensure the patient safety.

List of Registered Medical Devices



	License number	License Expiry Date	Device name	Device Model	Physical Manufacturer	Legal Manufacturer	Authorize Representative	Authorize Representative NO	HS Cood
613	MD-BH-2020000010	5-Feb-21	FreeGo Enteral Feeding Kit	S795	Abbott, Carbury Point, Finisklin Business and Technology Park, Sligo Ireland	Abbott, Carbury Point, Finisklin Business and Technology Park, Sligo Ireland	Wael Pharmacy	38883191	9018.90.90
614	MD-BH-2020000011	26-May-24	Mobile C-arm X-ray Product	OEC One CFD	GE HUALUM MEDICAL SYSTEMS CO. Ltd N 1 Yong North Road Beijing Economic Technological Development Zone BEIJING 100176 CHINA	GE HUALUM MEDICAL SYSTEMS CO. Ltd N 1 Yong North Road Beijing Economic Technological Development Zone BEIJING 100176 CHINA	General Medical	39907141	90221400
615	MD-BH-2020000012	29-Jun-21	Acuvue Revitaens MPDS 60ML SC W\LC	9608X	AMO (Hangzhou) Co., Ltd Road No.4 Hangzhou Economic & Technological Development Zone, Hangzhou, Zhejiang 310018, China	Block B, Liffey Valley Office Campus, Quarryvala, D22 XOY3 Co. Dublin, Ireland	Wael Pharmacy	38883191	3307900000
616			Acuvue Revitaens MPDS 100ML SC W\LC						
617			Acuvue Revitaens MPDS 360ML SC W\LC						
618	MD-BH-2020000013	5-Feb-21	Flexitainer 1000 ml	M240	Abbott, Carbury Point, Finisklin Business and Technology Park, Sligo Ireland	Abbott, Carbury Point, Finisklin Business and Technology Park, Sligo Ireland	Wael Pharmacy	38883191	9018.39.00
619	MD-BH-2020000015	7-Jan-22	BD Vacutainer Z(No Addictive) Plus Urine Tubes	368501	Becton, Dickinson and Company Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom	Becton, Dickinson and Company Belliver Industrial Estate, Belliver Way, Roborough, Plymouth, PL6 7BP, United Kingdom	Wael Pharmacy	38883191	9018390000

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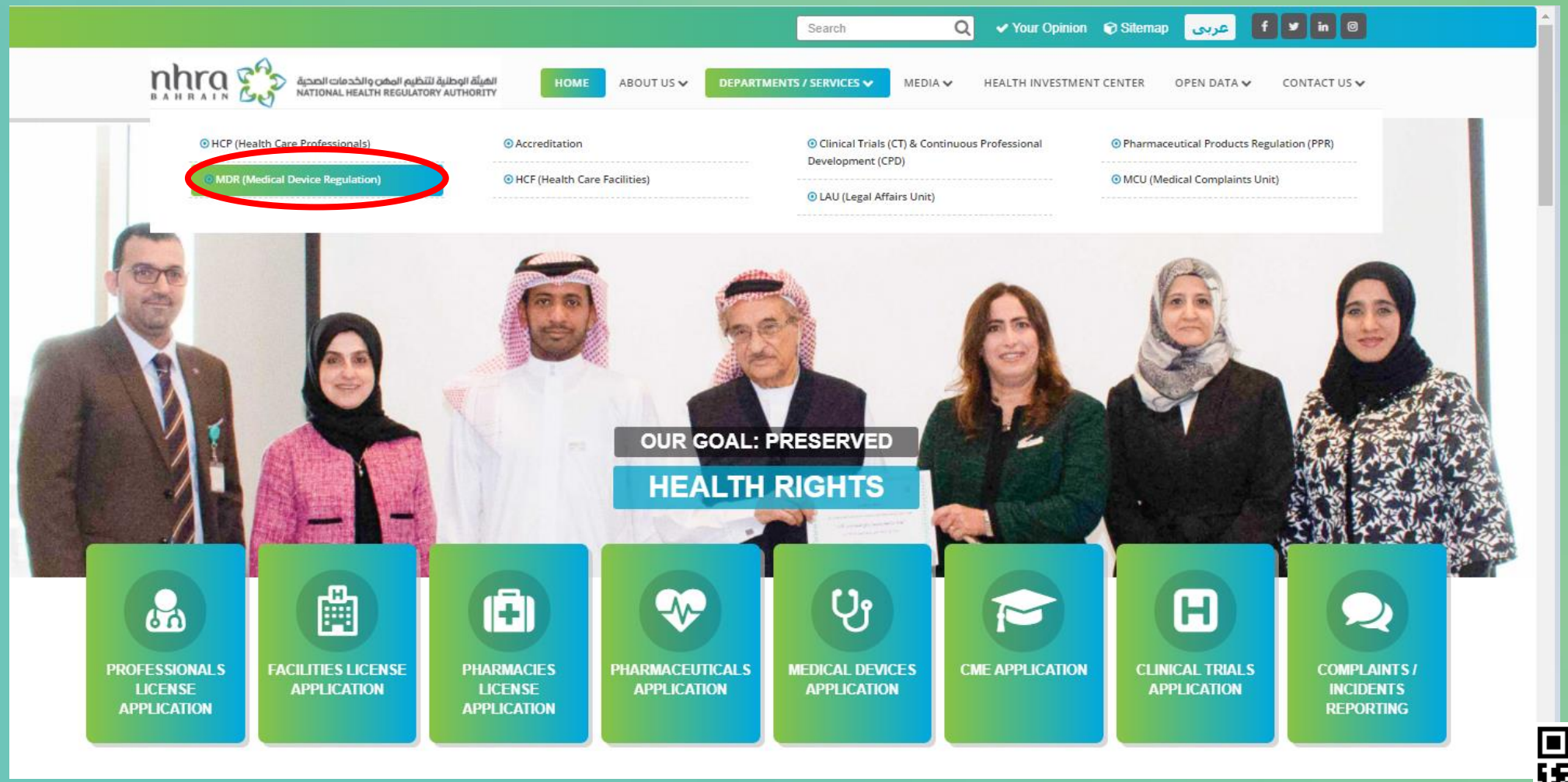
List of Registered Medical Devices



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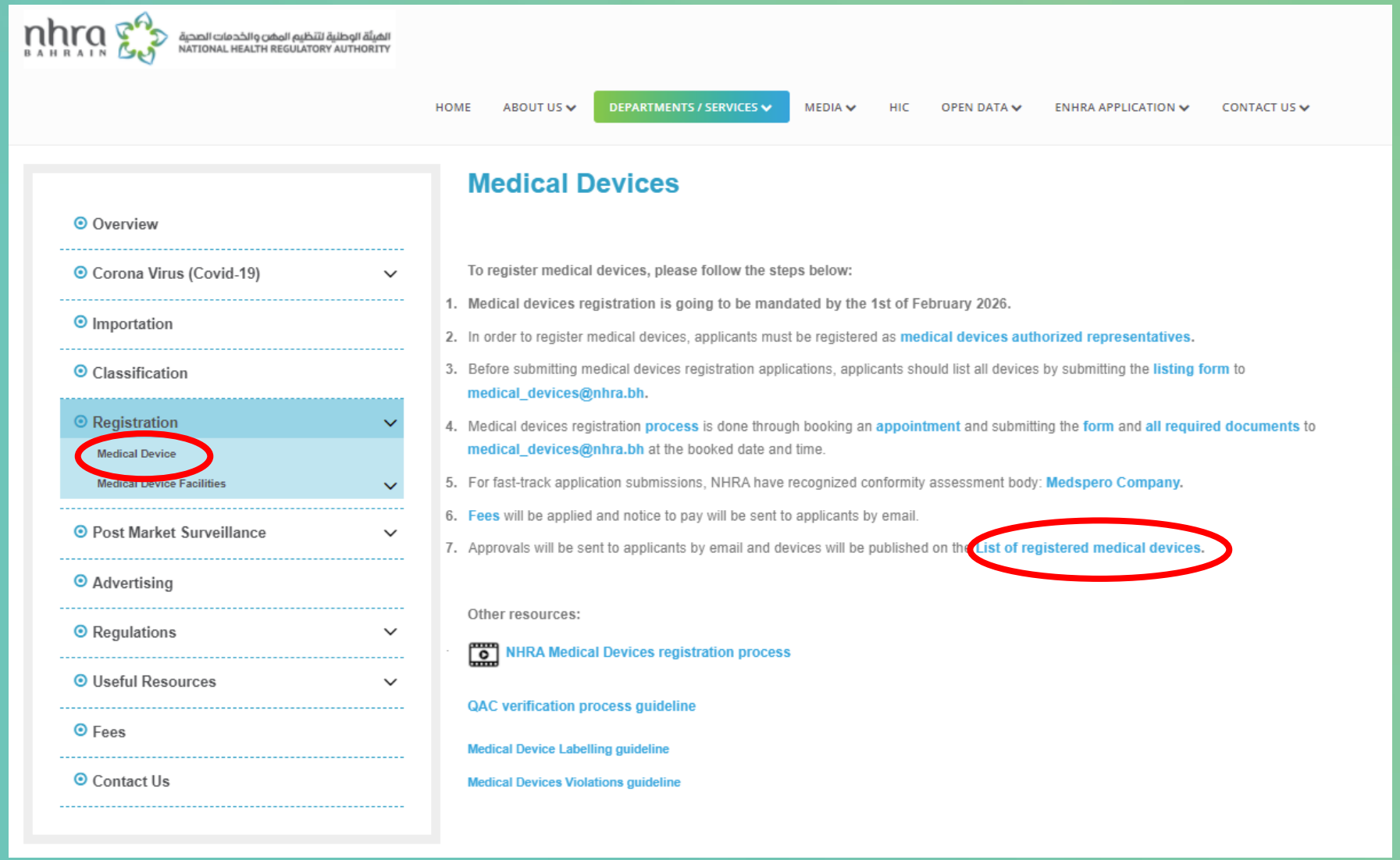
List of Registered Medical Devices



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Important points to know before applying for medical device registration

- Only NHRA registered authorized representatives can apply for medical device registration
- All medical devices should be registered regardless of its risk classification
- Registration is not linked to importation process whether HS code is regulated by NHRA or not.
- Accessories/spare parts cannot be registered.
- Fees are applied

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Listing

- List all medical devices that you intend to import in the future.
- Listing form is available on NHRA website.
- Includes medical device details.
- Filled listing form needs to be sent through email to medical_Devices@nhra.bh without appointment.

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الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

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مكتب الرئيس التنفيذي
Chief Executive Office

Circular No. (3) 2018

Date: 19 March 2018

To All Healthcare Facilities in the Kingdom

Subject: National Registry of Medical Devices

To comply with Article 4 of Law No. 38 of 2009 regarding the establishment of the National Health Regulatory Authority, we at NHRA are in the planning phase to establish a National Registry for Medical Devices. This registry will enable us to allocate medical devices once notifications regarding medical devices published from manufacturers/ authorites inorder to comply with international quality standards.

All healthcare facilities are requested to complete the details in the attached form and send them by e-mail to: Medical_devices@nhra.bh no later than one month after the date of issue of this circular.

For more information please do not hesitate to contact us on : 17113258 - 17113299

Thank you, for your continuous support in making healthcare safe in the Kingdom of Bahrain.

تعميم رقم (3) لسنة 2018

التاريخ: 19 مارس 2018 م

إلى جميع المؤسسات الصحية بالمملكة

الموضوع: إنشاء سجل وطني للأجهزة والمستلزمات الطبية

تعتزم الهيئة عن إنشاء سجل وطني للأجهزة والمستلزمات الطبية وذلك تطبيقاً للمادة (4) البند 8 من قانون 38 لسنة 2009 بشأن إنشاء الهيئة الوطنية لتنظيم المهن والخدمات الصحية والذي يسند إلى الهيئة مهمة التأكد من إستيفاء الأجهزة والمستلزمات الطبية المستخدمة في المؤسسات للمعايير والمواصفات الدولية المعتمدة، حيث سيمكن السجل الهيئة من تتبع الأجهزة في حال ورود أي إخطارات بشأنها من الجهة المصنعة / الرقابية.

وعليه ترجو الهيئة من جميع المؤسسات الصحية بملئ جميع البيانات في الاستمارة المرفقة وإرسالها عبر البريد الالكتروني: Medical_devices@nhra.bh بمدة أقصاها شهر من تاريخ التعميم.

ولمزيد من المعلومات يمكنكم التواصل معنا عبر الأرقام التالية: 17113258 – 17113299

ولكم جزيل الشكر والتقدير على تعاونكم الدائم في الارتقاء بالخدمات الصحية بالمملكة.

الدكتورة مريم عذبي الجلاهمة
الرئيس التنفيذي

Tel : +973 17 11 33 33
Fax : +973 17 11 33 59
P. O. Box : 11464, Manama
Kingdom of Bahrain
eMail : info@nhra.bh
Website : www.nhra.bh

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Process of Medical Device Registration

Authorized Representative reads guideline

Authorized Representative lists all devices

Authorized Representative prepare required documents

Authorized Representative books an appointment through NHRA Microsoft Booking

Authorized Representative submits documents at time of appointment through email to medical_devices@nhra.bh

NHRA sends Application notice to pay

NHRA review the documents

Requirements Fulfilled

NO

Reverted back to applicant to fufill the remaining requirements within 6 months and 2 more submissions

NO

Reject

Yes

Registration license Notice to Pay

Yes

Issue License

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Medical Device Registration Requirements

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What is meant by official letters and what do NHRA requires to be included in these letters?

- Full address of all entities included in the letter.
- Reference to the medical devices being applied for registration.
  - Scope
  - Medical device name and model
- Signature/electronic signature and Stamp of the issuer.
- To be valid letter (if applicable).
- To be Issued by the required issuer.

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Legal Manufacturer and Physical Manufacturer

legal manufacturer symbol

Who is the legal manufacturer?

- Legal entity responsible for the product to be placed on the market under its name.
- Found on the artwork of medical devices.

Who is the Physical manufacturer?

- Manufacturing site.

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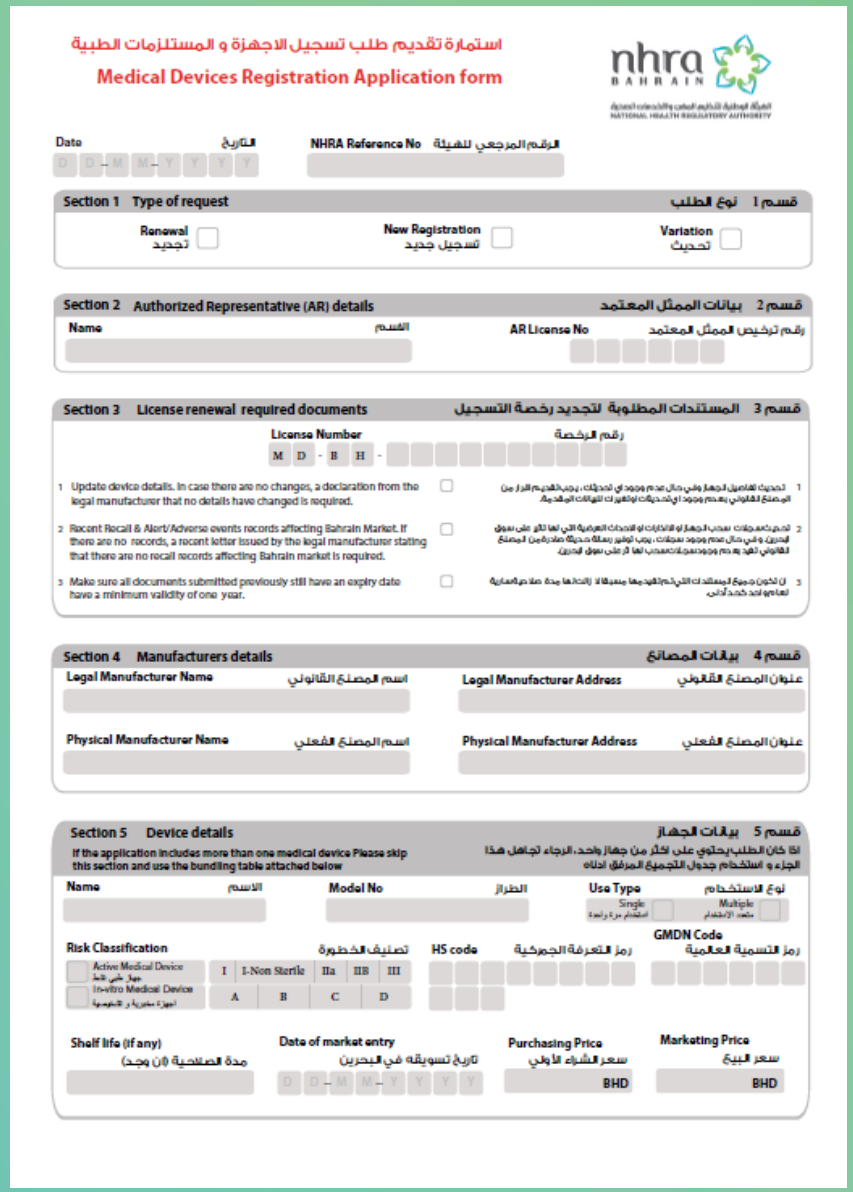
1. Application Form

AR, Manufacturer, and device details

Authorized Representative

No blank fields
Electronically filled



استمارة تقديم طلب تسجيل الاجهزة و المستلزمات الطبية

Medical Devices Registration Application form

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Date التاريخ D D – M M – Y Y Y Y

NHRA Reference No الرقم المرجعي للهيئة

Section 1 Type of request قسم 1 نوع الطلب

Renewal تجديد ☐ New Registration تسجيل جديد ☐ Variation تحديث ☐

Section 2 Authorized Representative (AR) details قسم 2 بيانات الممثل المعتمد

Name الاسم AR License No رقم ترخيص الممثل المعتمد

Section 3 License renewal required documents قسم 3 المستندات المطلوبة لتجديد رخصة التسجيل

License Number رقم الرخصة M D - B H -

1 Update device details. In case there are no changes, a declaration from the legal manufacturer that no details have changed is required. ☐ 1 تحديث تفاصيل الجهاز وفي حال عدم وجود اي تحديثات، يجب تقديم اقرار من المصنع القانوني بعدم وجود اي تحديثات لم تظهر في البيانات المقدمة.

2 Recent Recall & Alert/Adverse events records affecting Bahrain Market. If there are no records, a recent letter issued by the legal manufacturer stating that there are no recall records affecting Bahrain market is required. ☐ 2 تحديث بأحدث سجلات سحب الجهاز او الانذارات او التحذيرات العرضية التي لها تأثير على سوق البحرين. وفي حال عدم وجود سجلات، يجب توفير رسالة حديثة صادرة من المصنع القانوني تفيد بعدم وجود سجلات سحب لها أثر على سوق البحرين.

3 Make sure all documents submitted previously still have an expiry date have a minimum validity of one year. ☐ 3 ان تكون جميع المستندات التي تم تقديمها سابقا لا تزال لها مدة صلاحية لعام واحد كحد أدنى.

Section 4 Manufacturers details قسم 4 بيانات المصانع

Legal Manufacturer Name اسم المصنع القانوني Legal Manufacturer Address عنوان المصنع القانوني

Physical Manufacturer Name اسم المصنع الفعلي Physical Manufacturer Address عنوان المصنع الفعلي

Section 5 Device details قسم 5 بيانات الجهاز

If the application includes more than one medical device Please skip this section and use the bundling table attached below

اذا كان الطلب يحتوي على اكثر من جهاز واحد، الرجاء تجاهل هذا الجزء و استخدام جدول التجميع المرفق ادناه

Name الاسم Model No الطراز Use Type نوع الاستخدام Single Multiple

Risk Classification تصنيف الخطورة

Active Medical Device جهاز طبي فعال	I	I-Non Sterile	IIa	IIb	III
In-vitro Medical Device اجهزة مخبرية و تشخيصية	A	B	C	D	

HS code رمز التعرفة الجمركية GMDN Code رمز التسمية العالمية

Shelf life (if any) مدة الصلاحية (ان وجد) Date of market entry تاريخ تسويقه في البحرين D D – M M – Y Y Y Y

Purchasing Price سعر الشراء الأولي BHD Marketing Price سعر البيع BHD

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Medical Device Registration Requirements

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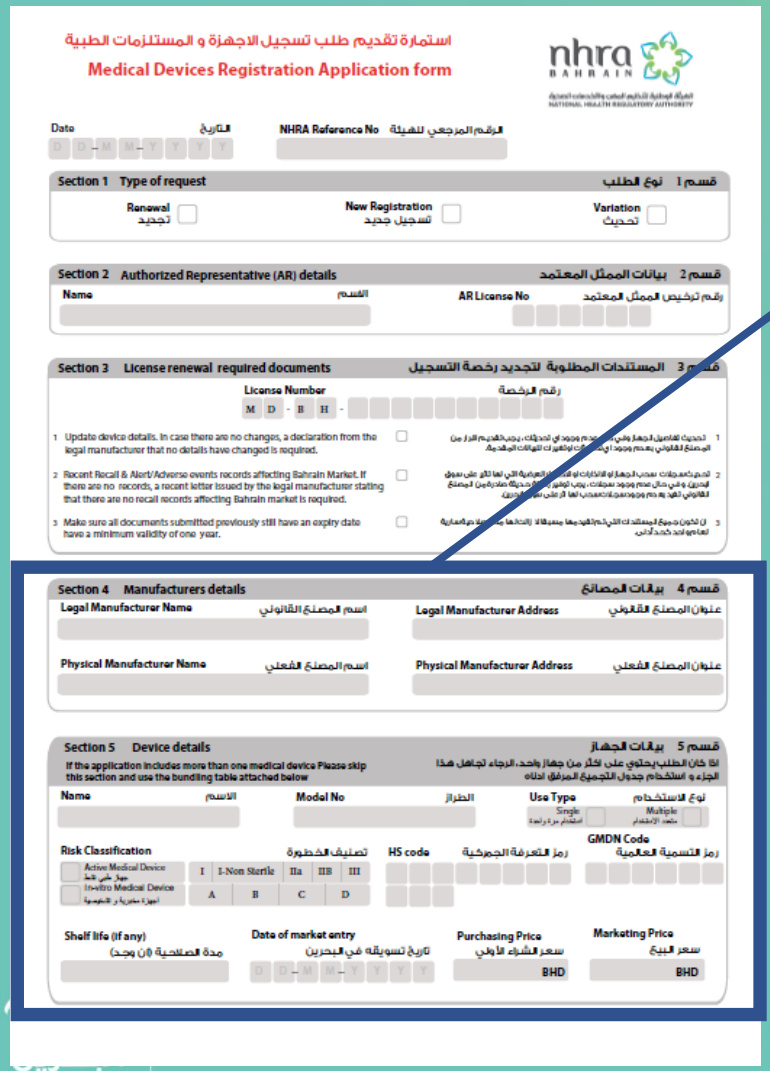
1. Application Form



استمارة تقديم طلب تسجيل الاجهزة و المستلزمات الطبية
Medical Devices Registration Application form

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Date التاريخ — NHRA Reference No الرقم المرجعي للهيئة

Section 1 Type of request — قسم 1 نوع الطلب
Renewal تجديد | New Registration تسجيل جديد | Variation تحديث

Section 2 Authorized Representative (AR) details — قسم 2 بيانات الممثل المعتمد
Name الاسم | AR License No رقم ترخيص الممثل المعتمد

Section 3 License renewal required documents — قسم 3 المستندات المطلوبة لتجديد رخصة التسجيل
License Number رقم الرخصة
MD-BH-

1 Update device details. In case there are no changes, a declaration from the legal manufacturer that no details have changed is required.
2 Recent Recall & Alert/Adverse events records affecting Bahrain Market. If there are no records, a recent letter issued by the legal manufacturer stating that there are no recall records affecting Bahrain market is required.
3 Make sure all documents submitted previously still have an expiry date have a minimum validity of one year.

Section 4 Manufacturers details — قسم 4 بيانات المصانع
Legal Manufacturer Name اسم المصنع القانوني | Legal Manufacturer Address عنوان المصنع القانوني
Physical Manufacturer Name اسم المصنع الفعلي | Physical Manufacturer Address عنوان المصنع الفعلي

Section 5 Device details — قسم 5 بيانات الجهاز
If the application includes more than one medical device Please skip this section and use the bundling table attached below
اذا كان الطلب يحتوي على اكثر من جهاز واحد، الرجاء تجاهل هذا الجزء و استخدام جدول التجميع المرفق ادناه

Name الاسم | Model No الطراز | Use Type نوع الاستخدام: Single استخدام مرة واحدة / Multiple متعدد الاستخدام

Risk Classification تصنيف الخطورة:
- Active Medical Device جهاز طبي نشط: I, I-Non Sterile, IIa, IIB, III
- In-vitro Medical Device اجهزة مخبرية و تشخيصية: General IVD, A, B, C, D

HS code رمز التعرفة الجمركية | GMDN Code رمز التسمية العالمية

Shelf life (if any) مدة الصلاحية (ان وجد)
Date of market entry تاريخ تسويقه في البحرين: D D – M M – Y Y Y Y
Purchasing Price سعر الشراء الأولي: BHD
Marketing Price سعر البيع: BHD

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2. Technical Details

- User Manual, Catalogue
- Medical device description.
- Medical device specifications.

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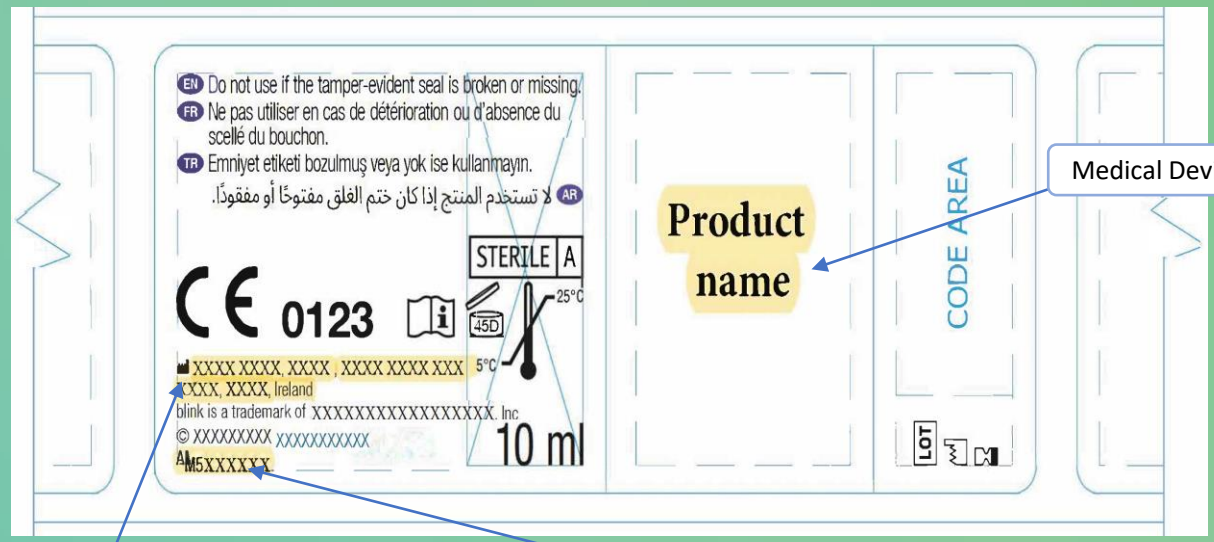
3. Artwork

Outer package of the medical device

- Medical device name.
- Legal Manufacturer name and address.
- Reference/model number.



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4. Authorization Letter OR Agreement

Official letter authorizing the applicant/authorized representative to register, import and sell the medical device in the Kingdom of Bahrain.

Legal Manufacturer

Authorized Representative

Needs to include the medical devices name and model or scope that covers them.

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5. Relationship letter

Official Letter explaining who is the physical manufacturer/s and the regional distributor (Invoice issuer).

Legal Manufacturer

Needs to include the medical devices name and model or scope that covers them.

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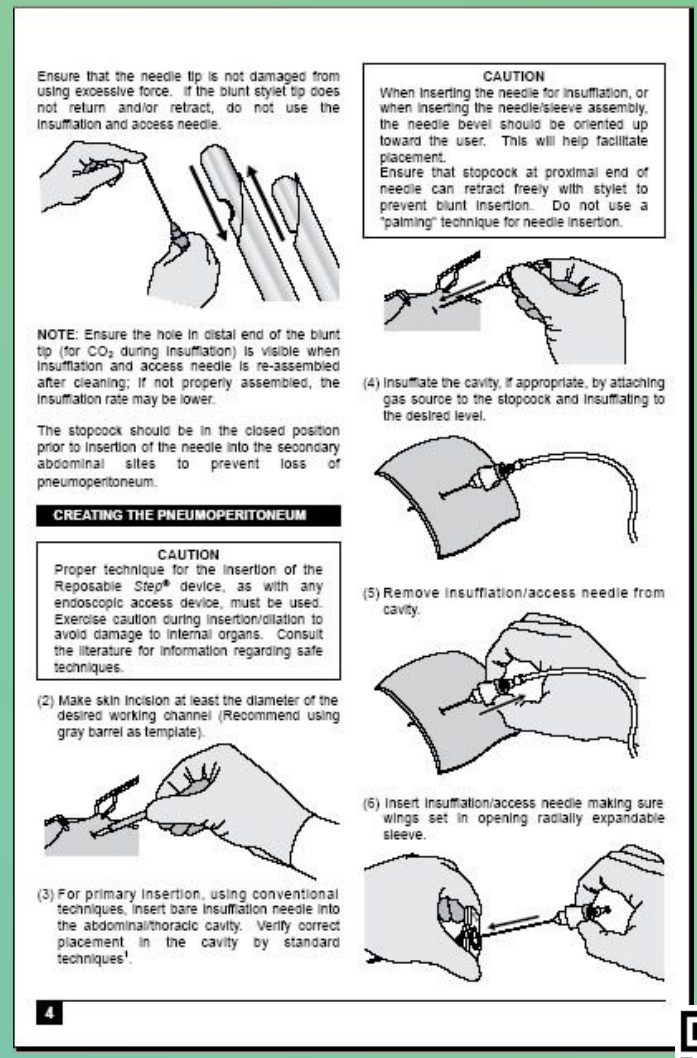
6.Instruction for use (ex: Leaflet)

Clear instruction on how to use the medical device.

Legal Manufacturer



Ensure that the needle tip is not damaged from using excessive force. If the blunt stylet tip does not return and/or retract, do not use the insufflation and access needle.

NOTE: Ensure the hole in distal end of the blunt tip (for CO_2 during insufflation) is visible when insufflation and access needle is re-assembled after cleaning; if not properly assembled, the insufflation rate may be lower.

The stopcock should be in the closed position prior to insertion of the needle into the secondary abdominal sites to prevent loss of pneumoperitoneum.

CREATING THE PNEUMOPERITONEUM

CAUTION
Proper technique for the insertion of the Reposable *Step*® device, as with any endoscopic access device, must be used. Exercise caution during insertion/dilation to avoid damage to internal organs. Consult the literature for information regarding safe techniques.

(2) Make skin incision at least the diameter of the desired working channel (Recommend using gray barrel as template).

(3) For primary insertion, using conventional techniques, insert bare insufflation needle into the abdominal/thoracic cavity. Verify correct placement in the cavity by standard techniques[1].

CAUTION
When inserting the needle for insufflation, or when inserting the needle/sleeve assembly, the needle bevel should be oriented up toward the user. This will help facilitate placement.
Ensure that stopcock at proximal end of needle can retract freely with stylet to prevent blunt insertion. Do not use a "palming" technique for needle insertion.

(4) Insufflate the cavity, if appropriate, by attaching gas source to the stopcock and insufflating to the desired level.

(5) Remove insufflation/access needle from cavity.

(6) Insert insufflation/access needle making sure wings set in opening radially expandable sleeve.

4

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7. List of marketed countries

Official letter listing the countries that the device is approved and marketed in.

Legal Manufacturer

Reference countries:

Saudi Arabia, USA, UK, Australia, Canada, Japan, Switzerland, Ireland, Denmark, New Zealand, France, Holland, Belgium.

Manufacturer Name

BioScience GmbH · Walsmühler Straße 10 · 15913 Dümmer

To whom it may concern

List of Countries

We herewith confirm that our product is used in the following countries:

Bulgaria
Bahrain
Switzerland
Germany
Denmark
Spain
Georgia
Hungary
Croatia
Italy
Jordan
KSA
Malaysia
Poland
Chile
Rumania
Sweden
Turkey
VAE
Vietnam
South Africa

Dümmer, 16.03.17

Kirsten Krollmann
Product Management

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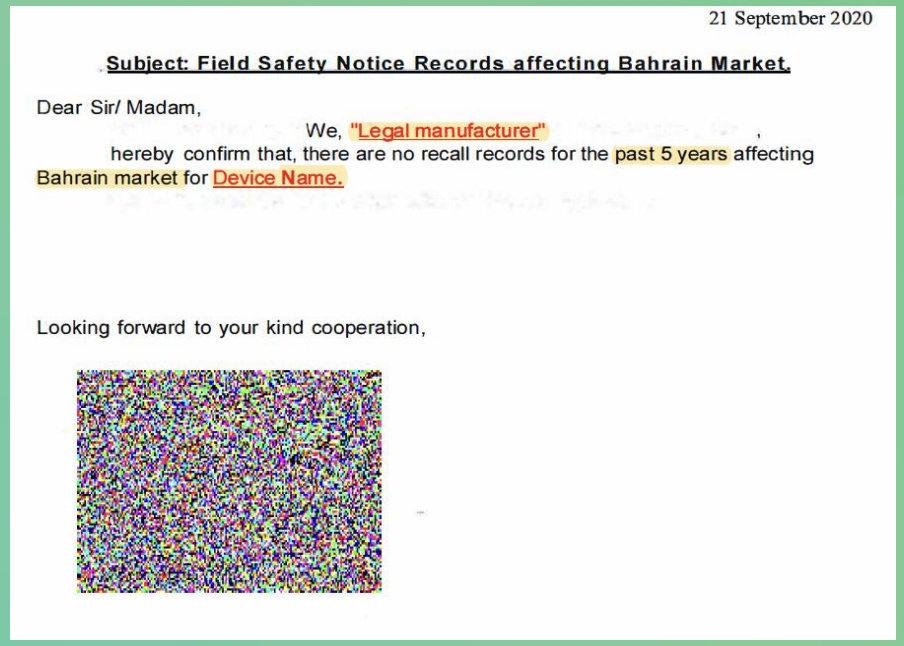
8. Field Safety Notice Records letter

Official letter listing the recalls and adverse events:

- Marketed in Bahrain > 5 years, Recalls affecting Bahrain only.
- Marketed in Bahrain < 5 years, Recalls affecting worldwide.

Legal Manufacturer

- If no records, FSN letter still needs to be provided.
- Needs to include the medical devices name and model or scope that covers them.



21 September 2020

Subject: Field Safety Notice Records affecting Bahrain Market.

Dear Sir/ Madam,

We, "Legal manufacturer" ,
hereby confirm that, there are no recall records for the past 5 years affecting Bahrain market for Device Name.

Looking forward to your kind cooperation,

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9. Recalls Report

Recalls affecting Bahrain Market

Official letter or email that for each record stating that it is closed

NHRA medical devices post market department

Recalls not affecting Bahrain Market

Official letter stating the actions taken regarding each record and whether it was closed

Legal Manufacturer

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10. List of End-users

Official Letter listing the End-users of the devices.

Authorized Represenative

Mandatory in case the medical device already entered in Bahrain Market.

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11. Quality Management System Certificate(QMS)

Certificate to proof that the manufacturer Quality Management system is as per international standard for medical devices

IAF accredited notified body.

Physical Manufacturer

ISO 13485 standard.
Scope of certificate covers the applied medical

bsi. Accredited notified body

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that: Physical Manufacturer Name & Address

Holds Certificate Number: MD 71XXX

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Head office functions including senior management directorate.
The design, manufacture, distribution, related post-production activities for programmable electrical medical systems including infusion pumps, infusion controllers, syringe pumps, pumps for medical vehicle use, enteral feeding pumps, filters, manifolds, administration sets for infusion, transfusion, enteral feeding and parenteral nutrition, software for the control and monitoring of infusions and data management and reusable accessories.
The design, control of manufacture, sales and related post production activities for filters, manifolds, access devices, administration sets for infusion, transfusion, enteral feeding, and parenteral nutrition.
The sales and distribution of sterile disposable syringes. Scope

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2002-12-20
Latest Revision Date: 2019-02-26

Effective Date: 2018-12-07
Expiry Date: 2021-12-06 validity

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12. Quality Assurance Certificate (QAC)

To certify that the medical device quality and safety is in conformity with medical devices international standards.

NANDO member notified body

Legal Manufacturer

- MDD, IVDD, MDR, IVDR
- Scope of certificate covers the applied medical
- Can be replaced by FDA certificate to foreign government.
- For class 1 non-sterile medical devices, a Declaration of Conformity can be submitted instead.

bsi. Accredited notified body

By Royal Charter

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 00XXX

Issued To: Legal manufacturer name & Address.

In respect of:

The design, development and manufacture of sterile and non-sterile orthopaedic joints, spinal and trauma implant systems, bioresorbable implant systems, sterile class IIa and non-sterile class IIa orthopaedic instruments

Those aspects of Annex II related to securing and maintaining sterility in the manufacture of sterile orthopaedic instrumentation

Scope

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: 1994-12-09 Date: 2019-02-27 Expiry Date: 2021-11-29 Validity

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bsi.

By Royal Charter

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. CE 54XXXX

Issued To:

Legal Manufacturer Name & Address

In respect of:

Product name

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4 and Commission Directive 2005/50/EC. The design conforms to the requirements of 93/42/EEC. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: 2009-09-01 Date: 2019-08-26 Expiry Date: 2024-05-26 validity

...making excellence a habit.

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13. EC Design Examination Certificate

Certification that the medical device design is in conformity with medical devices international standards

NANDO member notified body

Legal Manufacturer

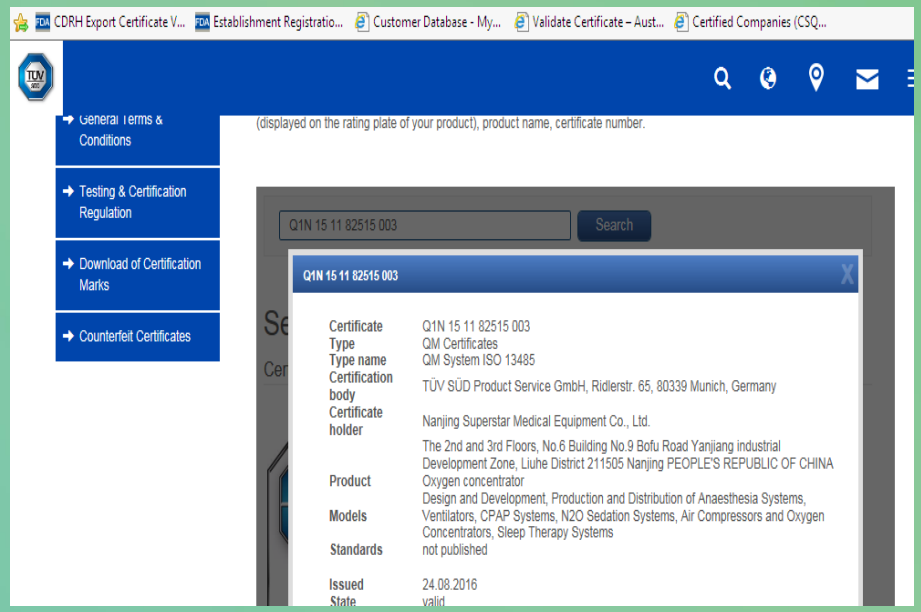
- For class III and IVD class D medical devices.
- MDD, IVDD, MDR, IVDR
- Scope of certificate covers the applied medical
- Can be replaced by FDA certificate to foreign government.

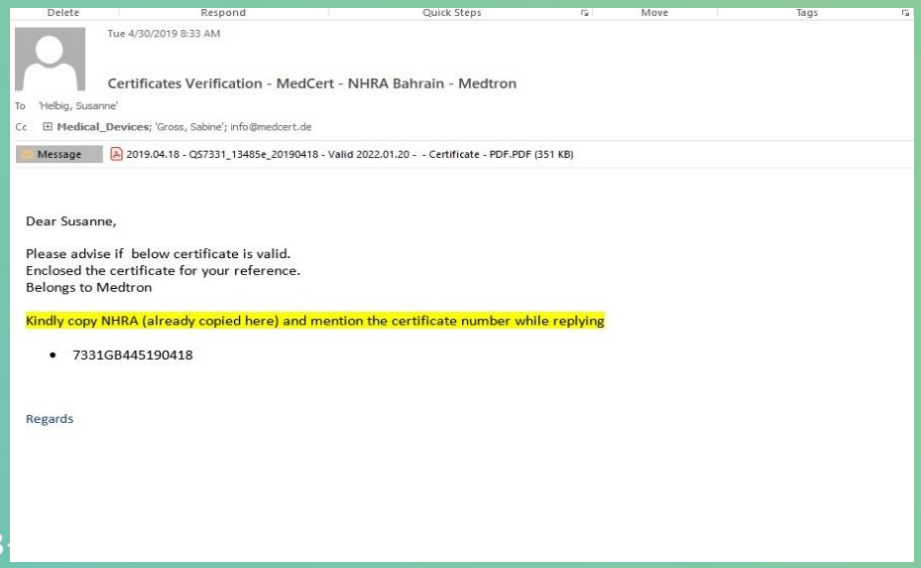
14. Verification of quality documents

1. Online through the website of Notifying body.

2. By sending an email to the notifying Body and NHRA should be in the mailing Loop.

medical_devices@nhra.bh





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15. Free Sale Certificate

Certification of compliance with the country's regulations and the ability to freely market the device.

Competent Authority in the country of origin or one of the reference countries

Legal Manufacturer

Medicines & Healthcare products Regulatory Agency

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
mhra.gov.uk

SAE XXX/XXXXXX/1

29/06/2020 09:00:09

Medicines and Healthcare Products Regulatory Agency
On behalf of the Secretary of State for Health and Social Care

CERTIFICATE OF FREE SALE FOR EXPORTATION OF MEDICAL PRODUCTS TO

BAHRAIN

It is hereby certified that, on the basis of information provided, the products named below and detailed in the attached schedule (if applicable), which are manufactured by; Legal Manufacturer: **XXXXXXXXX**, XXXXXXXXXX, UNITED KINGDOM. Physical manufacturers: **XXXXXXXXX**, XXXXXXXXXXX, UNITED KINGDOM. **XXXXXXXXXXXXX**, XXXXXXXXXXX, China, have been affixed with the CE mark under the Medical Devices Directive 93/42/EEC as transposed into UK legislation (UK Medical Devices Regulations 2002 SI No. 618, as amended), and therefore may be freely sold in all member states of the European Economic Area including the United Kingdom.

See attached schedule

Where appropriate, Certificates of Free Sale are issued as a service to UK exporters. A Certificate of Free Sale should not be taken as a Government endorsement of any product that is referred to on the certificate.

Yours sincerely,

Gbemisola Sunmon

Certificate of Free Sale Administration Team
Signed on Behalf of MHRA

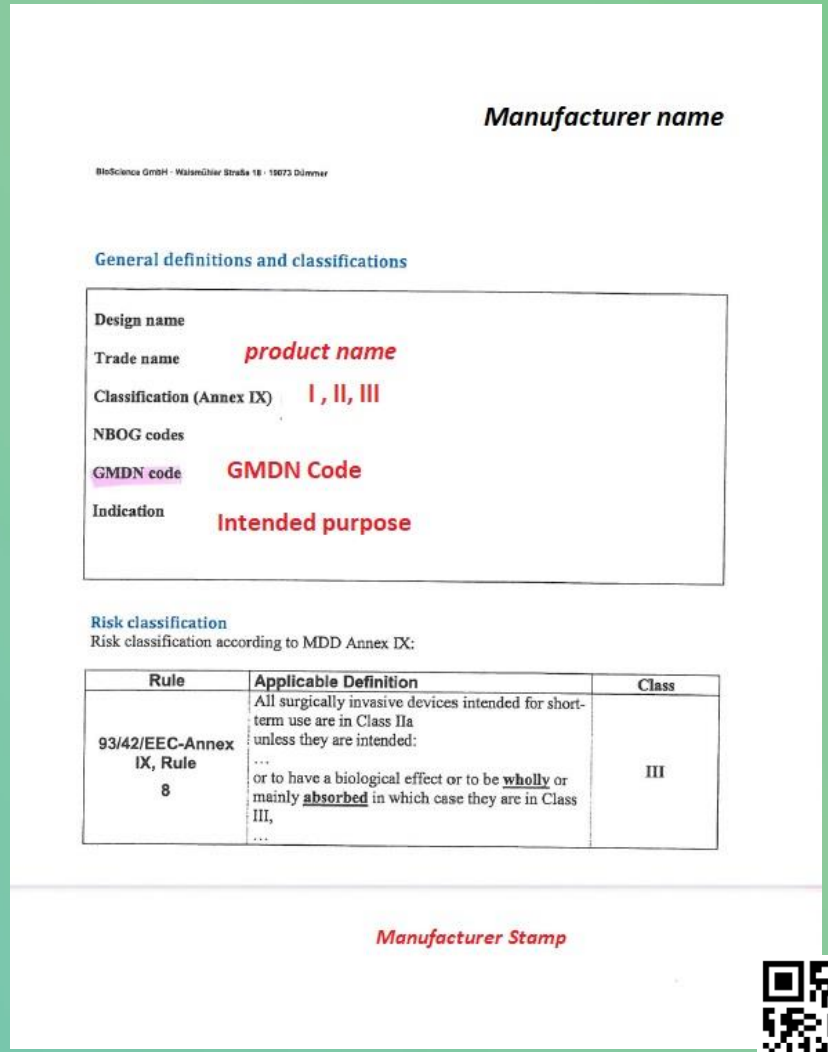
16. Declaration of conformity (DOC) or Declaration letter.

Declaration that the device meets with the European medical device standards.

Legal Manufacturer

Medical device name and model.

Risk classification and GMDN code.



Manufacturer name

BioScience GmbH · Walsmühler Straße 18 · 19073 Dümmer

General definitions and classifications

Design name	
Trade name	*product name*
Classification (Annex IX)	I , II, III
NBOG codes	
GMDN code	GMDN Code
Indication	Intended purpose

Risk classification

Risk classification according to MDD Annex IX:

Rule	Applicable Definition	Class
93/42/EEC-Annex IX, Rule 8	All surgically invasive devices intended for short-term use are in Class IIa unless they are intended: … or to have a biological effect or to be **wholly** or mainly **absorbed** in which case they are in Class III, …	III

Manufacturer Stamp

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17. Free from porcine derivatives letter

Official letter that the device is free from porcine derivatives

Legal Manufacturer

Not applicable for In Vitro Diagnostic (IVD) Medical devices.

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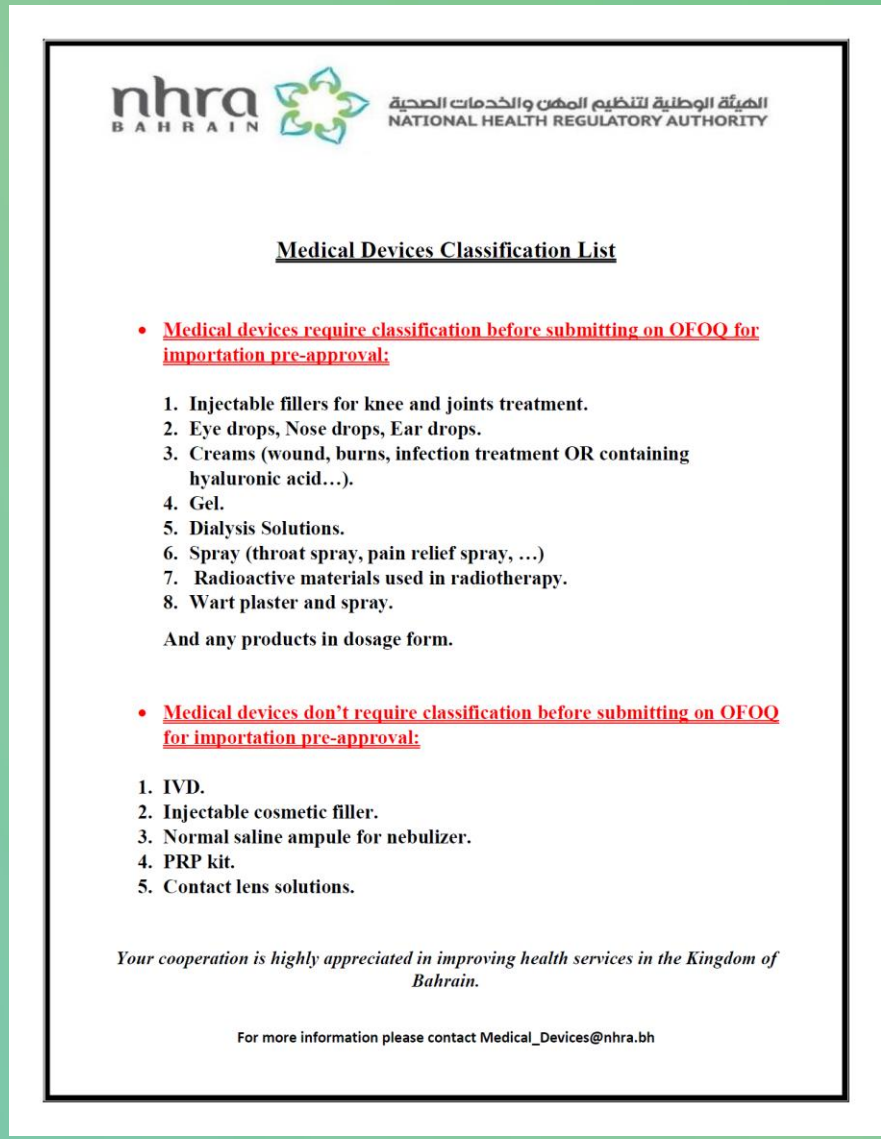
18. Classification letter

Official letter classifying the product as a medical device.

NHRA medical devices regulations department

Mandatory for the types of devices mentioned in the classification list.



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الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

Medical Devices Classification List

- **Medical devices require classification before submitting on OFOQ for importation pre-approval:**

1. Injectable fillers for knee and joints treatment.
2. Eye drops, Nose drops, Ear drops.
3. Creams (wound, burns, infection treatment OR containing hyaluronic acid…).
4. Gel.
5. Dialysis Solutions.
6. Spray (throat spray, pain relief spray, …)
7. Radioactive materials used in radiotherapy.
8. Wart plaster and spray.

And any products in dosage form.

- **Medical devices don't require classification before submitting on OFOQ for importation pre-approval:**

1. IVD.
2. Injectable cosmetic filler.
3. Normal saline ampule for nebulizer.
4. PRP kit.
5. Contact lens solutions.

Your cooperation is highly appreciated in improving health services in the Kingdom of Bahrain.

For more information please contact Medical_Devices@nhra.bh

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Time frame of reviewing medical devices registration applications

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- Regular route - 8 to 16 weeks.
- Fast track route – 4 to 8 weeks.

MEDSPERO
Scientific & Regulatory Consultancy

BAHRAIN

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2022 Registered devices
Until end of quarter2

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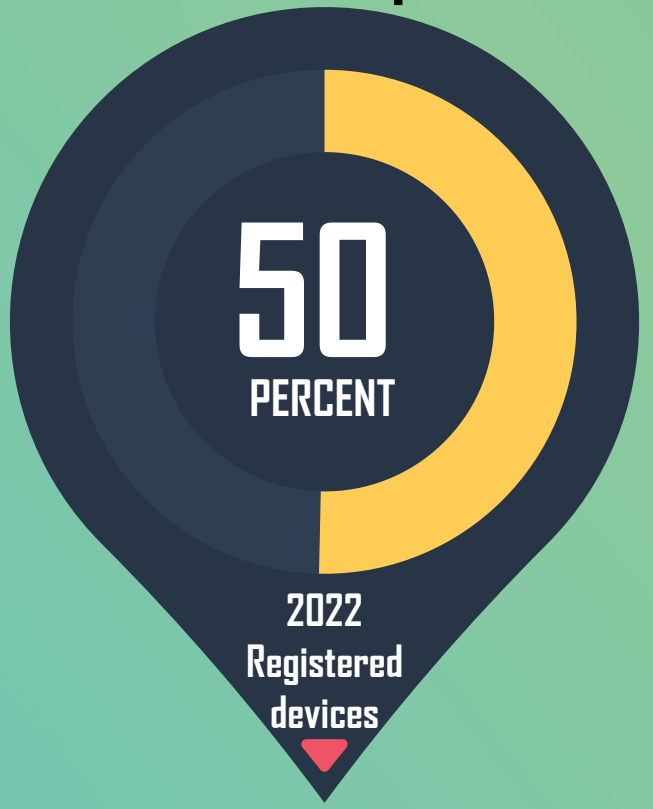
Statistics



377 DEVICES

OUT OF 740 DEVICES APPLIED in 2022 until end of quarter 2.

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NHRA License Variation and Renewal

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- Variation is any change that can happen to the medical device after registration. Example: Change in Artwork, Expiry of Quality documents.

- Renewal is done annually for all registered medical devices. Renewal Applications can be submitted 3 months from the expiry date.

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Thank You

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