



Medical Device Registration

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Presented by: Eng. Abdullatif Alnaser Medical Equipment Engineer NHRA



Website: www.nhra.bh

Tel.: +973-17113299





Kingdom of Bahrain 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.





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Importance and benefits of medical device

- 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.





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List of Registered Medical Devices



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1	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
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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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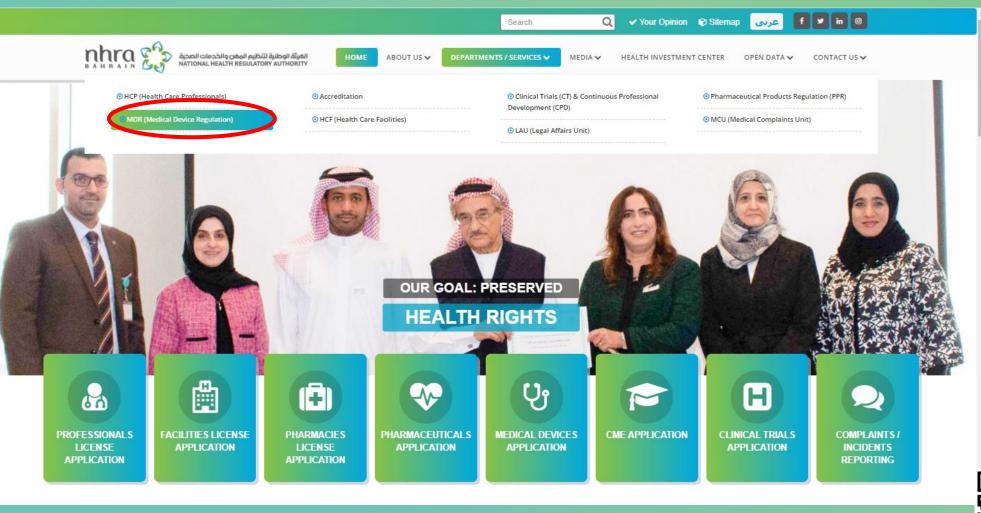
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List of Registered Medical Devices







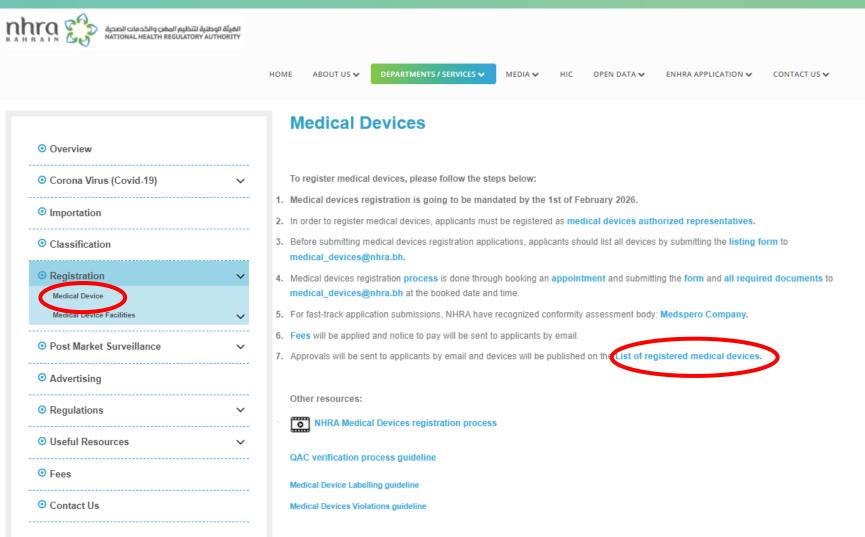
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Important points to know before applying for medical device registration



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 <u>medical Devices@nhra.bh</u> without appointment.



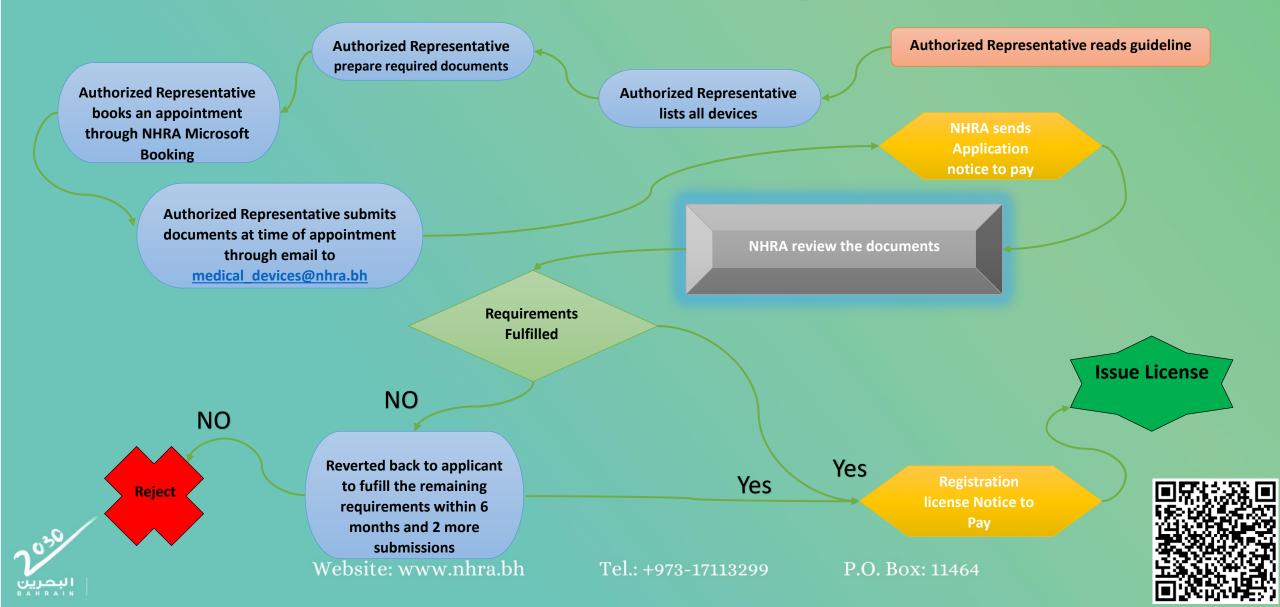


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Process of Medical Device Registration









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.





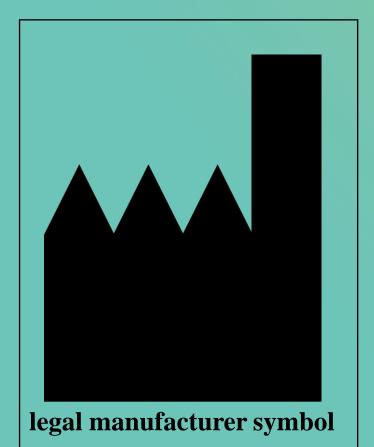
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Legal Manufacturer and Physical Manufacturer



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



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1. Application Form

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			سعر الشراء الأولي تاريخ	سعر البيع آ

Section 4 Manufactu	irers details				قسم 4 بيانات المصانع
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Physical Manufacturer N	لي lame	اسم المصنع الفعا	Physica	l Manufacturer Address	عنوان المصنع الفعلي
Section 5 Device de	etails				قسم 5 بيانات الجهاز
If the application includes this section and use the bu			هذا		اذا كان الطلب يحتوي على اكثر الجزء و استخدام جدول التجميع
Name	الاسم	Model No	إز	Use Type الطر	نوع الاستخدام
				Single ستخدام مرة واحدة	Multiple متعدد الاستخدام
					GMDN Code
Risk Classification		تصنيف الخطورة	HS code	رمز التعرفة الجمركية	رمز التسمية العالمية
جهاز طبي نشط	I I-Non Sterile	IIa IIB III			
In-vitro Medical Device اجهزة مخبرية و تشخيصية	General IVD A	B C D			
Shelf life (if any)	Date	of market entry		Purchasing Price	Marketing Price
لاحية (ان وجد)	مدة الصا	قه في البحرين	تاريخ تسوير	سعر الشراء الأولي	سعر البيع
		D – M M – Y Y		BHD	BHD





2. Technical Details



User Manual, Catalogue Medical device description. Medical device specifications. FLIGHT MEDICAL INNOVATIONS Ltd.

FLIGHT 60 VENTILATOR

Service Manual



V60-00002-18 Rev. A

May 2011



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Tel.: +973-17113299





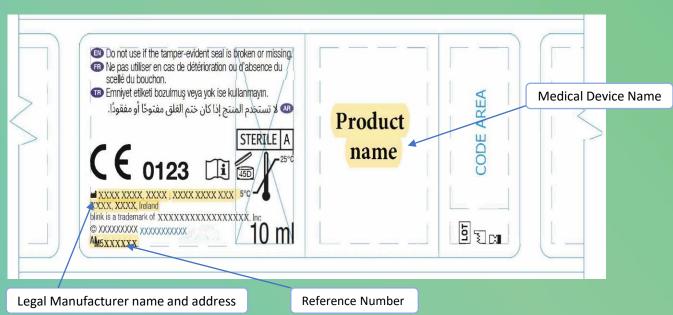


3. Artwork

1		
	7/	

Outer package of the medical device

- **Solution** Medical device name.
- **Solution** Legal Manufacturer name and address.
- **Solution** 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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CAUTION

When inserting the needle for insufflation, or

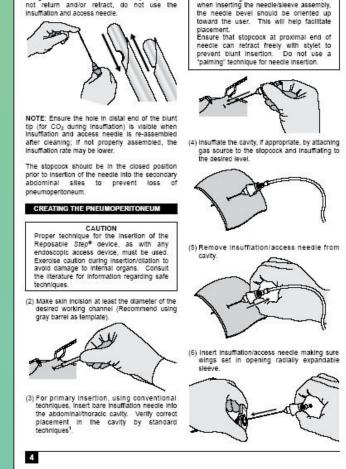
6.Instruction for use (ex: Leaflet)



Clear instruction on how to use the medical device.



Legal Manufacturer





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P.O. Box: 11464

Ensure that the needle tip is not damaged from

using excessive force. If the blunt stylet tip does







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 GnOH - Watamühler Boafte 18 - 19072 Dünner	
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 Rumanla	
Sweden Turkey VAE	
Vietnam South Africa	
7	
Dürfingf, 16.03.17	
Kirsten Krollmann	



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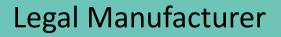


8. Field Safety Notice Records letter

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.







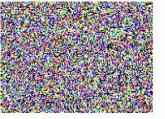
- If no records, FSN letter still needs to be provided.
- Needs to include the medical devices name and model or scope that covers them.



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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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مملكة البحريـن Kingdom of Bahrain

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





Certificate of Registration

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

SearphA 5

Holds Certificate Number:

This is to certify that:

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:

Physical Manufacturer Name

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. Scone

I M SIA

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**

Page: 1 of 3

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مملكة البحريـن Kingdom of Bahrain

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.



		non-sterile orthopaedic joints, sp ems, sterile class IIa and non-ster
class IIa orthopaedic instrum		ens, sterie class 11a and non-ster
Those aspects of Annex II rela sterile orthopaedic instrumen	tation	aining sterility in the manufacture
	Scope	
	n 4. The quality assurance system	the requirements of Council Directive n meets the requirements of the directive. ertificate is required.
For and on behalf of BSI, a Notified B	Body for the above Directive (Noti	fied Body Number 2797):
\sim		
1.31		
Albert Roossien, Regulatory Lead		
First Issued: 1994-12-09	Date: 2019-02-27	Expiry Date: 2021-11-29 Va
		making excellence a ha Page 1
		回安站。
		198 BA

Accredited notified body

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

No.

Issued To:

CE 00XXX

EC Certificate - Full Quality Assurance System

al manufacturer name

Tel.: +973-17113299











EC Design-Examination Certificate Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. Issued To: CE 54XXXX 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):

jang C Stade

Gary E Slack, Senior Vice President Medical Devices

First Issued: 2009-09-01

Date: 2019-08-26

Expiry Date: 2024-05-26 validity

Website: www.nhra.bh

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Page 1 of 8





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.

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14. Verification of quality documents

- Online through the website of Notifying body.
- 2. By sending an email to the notifyingBody and NHRA should be in the mailingLoop.
- medical devices@nhra.bh

🚖 🏧 CDRH Export Certificate V 🔤 Es	stablishment Registratio 🧃 Custor	mer Database - My	🧃 Validate Certificate – Aust	. 🧧 Certified Com	panies (CSQ	
General Lerms &	(displayed on the rating plate o	of your product), produc	t name, certificate number.	Q	00	⊻ :
Conditions						
→ Testing & Certification Regulation	Q1N 15 11 82515 003		Search			
→ Download of Certification Marks	Q1N 15 11 82515 003					X
Tue 4/30/2019 8:33 AM	Cert Type ame Cert Type ame Certificate Pype ame Certification body Certificate holder Product Models Standards Issued State	Nanjing Superstar The 2nd and 3rd F Development Zone Oxygen concentia Design and Develo Ventilators, CPAP Concentrators, Sie not published 24.08.2016 valid Quick Steps	485 Service GmbH, Ridlerstr. 65, 8 Medical Equipment Co., Ltd. oors, No.6 Building No.9 Bofu , Luhe District 211505 Nanjing or pment, Production and Distribi Systems, N2O Sedation Syste ap Therapy Systems	Road Yanjiang indu PEOPLE'S REPUB ution of Anaesthesia ms, Air Compressors	strial ILIC OF CHINA Systems,	•
Cc Medical_Devices; 'Gross, Sabine						
Message 2019.04.18 - Q5733 Dear Susanne, Please advise if below certificat Enclosed the certificate for you Belongs to Medron		0 Certificate - PDF.	'DF (351 KB)			
Kindly copy NHRA (already cop	ied here) and mention the ce	ertificate number	while replying			
• 7331GB445190418						
Regards						



Tel.: +973





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, XXXXXXXXX, UNITED KINGDOM. Physical manufacturers: XXXXXXXXX, XXXXXXXXX, UNITED KINGDOM. XXXXXXXXXXXXXXX, XXXXXXXX, 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



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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.

	M	anufacturer name
BloScience GmbH - Waismühier St	alle 18 - 19073 Dümmer	
General definitio	ns and classifications	
Design name		
Trade name	product name	
Classification (Anne	x IX) , ,	
NBOG codes		
GMDN code	MDN Code	
Indication Ir	tended purpose	
Risk classification Risk classification ac	ording to MDD Annex IX:	
Rule	Applicable Definition	Class
93/42/EEC-Annex IX, Rule	All surgically invasive devices intender 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



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17. Free from porcine derivatives letter

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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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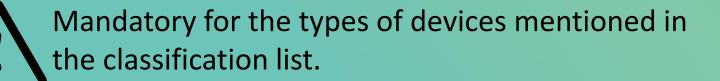
18. Classification letter



Official letter classifying the product as a medical device.



NHRA medical devices regulations department





الفيئة 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 nhrae is registration applications

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







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Kingdom of Bahrain

Statistics



51

PERCENT



2022 Registered devices

377 DEVICES

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



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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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