Quality Assurance Certificates and Verification Process Guideline

National Health Regulatory Authority (NHRA)

Kingdom Of Bahrain

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1. Definitions

- **CAB (Certifying Accredited Body):** The role of the Certifying Body is to conduct a conformity assessment under the relevant EU Directives. The conformity assessment usually involves an audit of the manufacturer's quality system and depending upon the particular classification of the device, a review of the relevant technical documentation provided by the manufacturer in support of the safety and performance claims for the device.

  Once the Certifying has determined a manufacturer has conformed to the relevant assessment criteria, it issues a certificate to show that the products assessed meet the requirements.

- **Certification QAC:** It is the provision by an independent body of written assurance (a certificate) that the product, service or system in question meets specific requirements. Certification is also known as third party conformity assessment.

  Many companies and organizations decide to get certified to one of ISO's management system standards, such as ISO 9001. This is a way of showing outsiders that the organization has an effective quality management system in place.

- **ISO 13485:** A standard that is an effective solution to meet the comprehensive requirements for a quality management system. Adopting ISO 13485 provides a practical foundation for manufacturers to address the regulations and responsibilities as well as demonstrating a commitment to the safety and quality of medical devices.

  ISO 13485 is a stand-alone QMS standard, derived from the internationally recognized and accepted ISO 9000 quality management standard series. ISO 13485 adapts the ISO 9000 process-based model for a regulated medical device manufacturing environment. While ISO 13485 is based on the ISO 9001 process model concepts of Plan, Do, Check, Act, it is designed for regulatory compliance. It is more prescriptive in nature and requires a more thoroughly documented quality management system.

ISO 13485 was written to support medical device manufacturers in designing quality management systems that establish and maintain the effectiveness of their processes. It ensures the consistent design, development, production, installation, and delivery of medical devices that are safe for their intended purpose.

- **CE Mark:** CE marking is the medical device manufacturer's claim that a product meets the essential requirements of all relevant European Directives and is a legal requirement to place a device on the market in the European Union.

- **Verification:** it is the process of checking the validity of the QAC by contacting the issuer certifying body to ensure the quality and good manufacturing of the medical device according to international standards.

2. Introduction

All Medical Devices that are being imported and marketed in the Kingdom of Bahrain should have a Quality Assurance Certificate (QAC) to ensure a good manufacturing process as per global standards and ensure patient safety and public health.

This guideline is intended to highlight the overall requirements and limitations for accepting a quality assurance certificate, in addition to the process of verifying the certificate before submitting it for NHRA approval and registration. International standards and recognized regulatory authority guidelines has been adapted in this guideline to harmonize NHRA regulations with global requirements.

3. General Rules

1. For importation pre-approval the following details stated in the certificate must match with the details in the invoice:
    a. Manufacturer name.
    b. Country of Origin.
    c. Scope of service.

2. For medical device registration the following details stated in the certificate must match with the details in the registration form:
    a. Manufacturer name.
    b. Country of Origin.
    c. Scope of service.

3. All certifying bodies issuing the quality assurance certificate should be recognized by the **EU** for CE certificate and **IAF** for ISO certificate, all certificates must be verified from the issuing body.

4. Submitting falsified certificate will cause the applicant to legal actions, therefore all certificate must be fist verified before submission to NHRA.

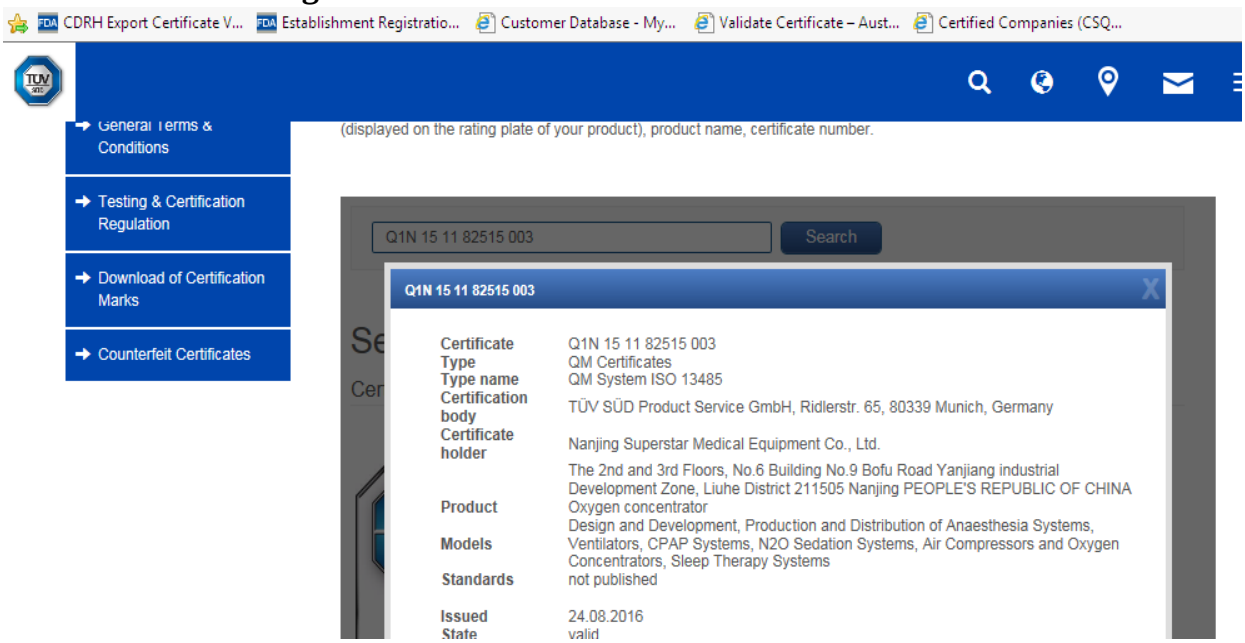
4. Verification Process

In order to verify the Quality Assurance Certificate and ensure its validity, applicant should contact the Certifying Body through one of the following process:

1. Send an email to the Certifying body mentioning the certificate number or attach the certificate and receive a reply conforming the validity, and NHRA should be in the mailing loop of verification.

2. Visit the website of the Certifying Body and check the validity of the certificate by searching either by certificate number or manufacturer name, and a capture of the online verification should be submitted with the request.

An example of online verifying ISO 13485 certificate issued by the Certifying body "TUV SUD" showing the certificate number and its status is valid.



To check if your certificates are issued by a recognized please visit "European Commission" website for CE certificate and "IAF" website for ISO certificate.

European Commission website

http://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=country.main

IAF website

https://www.iaf.nu//articles/IAF_MEMBERS_SIGNATORIES/4

This is an example of ISO 13485 certificate issued from BSI Certifying Body from United Kingdom, In order to check whether if it is recognized or not follow these steps:

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003 & EN ISO 13485:2012

This is to certify that:

Holds Certificate Number:

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 & EN ISO 13485:2012 for the following scope:

Design, development, control of manufacture and distribution of sterile medical devices made of hyaluronic acid with or without dextranomer

For and on behalf of BSI:

Frank Lee, EMEA Compliance & Risk Director

Original Registration Date: 22/01/2016
Latest Revision Date: 22/01/2016

Effective Date: 22/01/2016
Expiry Date: 21/01/2019

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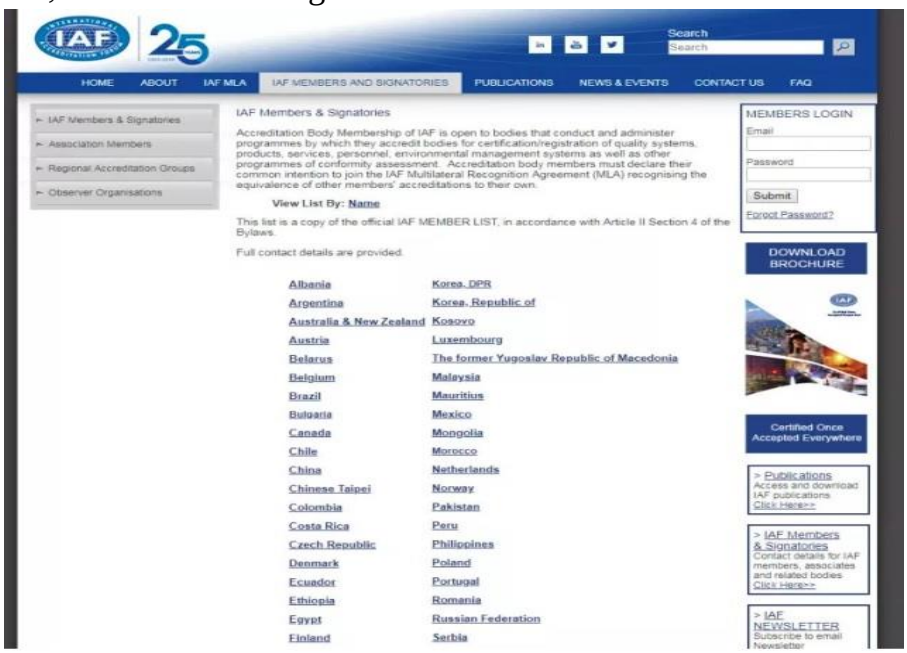
...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated online.
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 845 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

1. Visit IAF website.

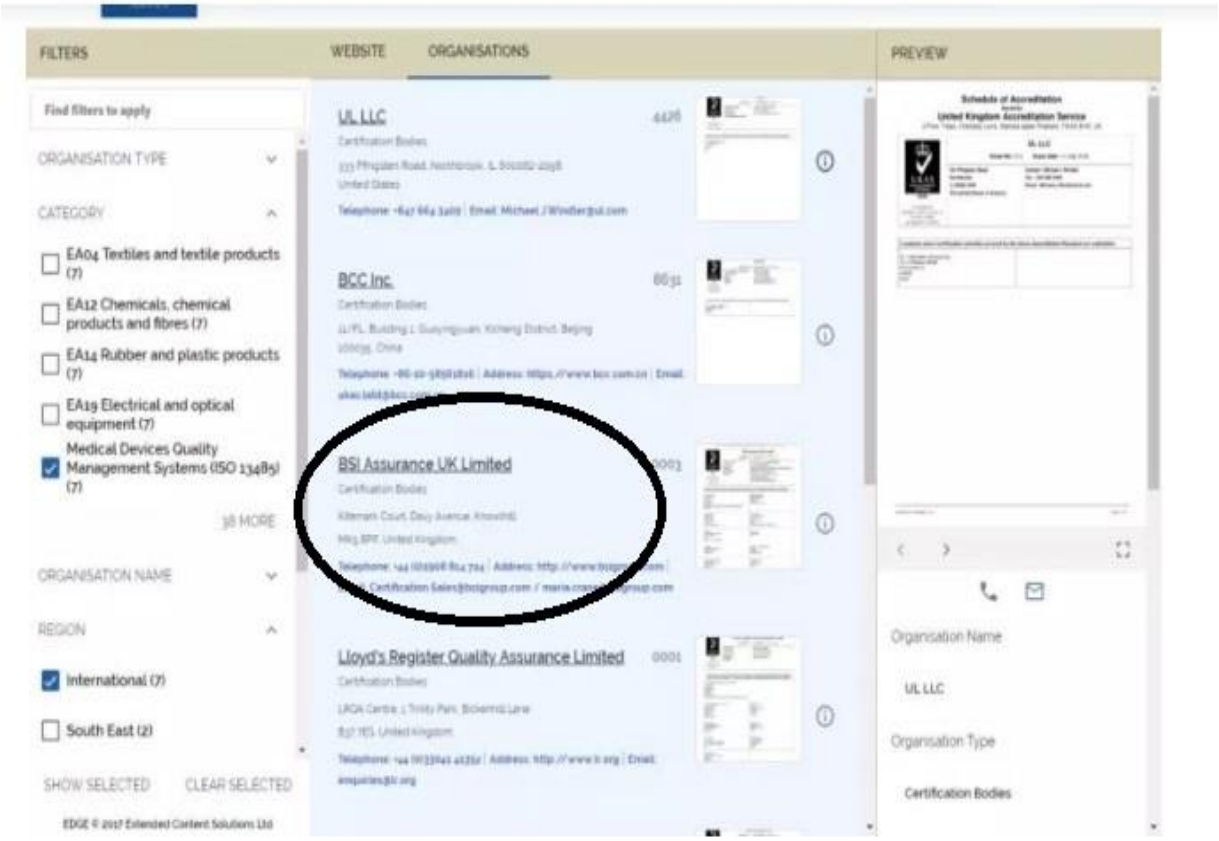
2. Go to the section **IAF MEMBERS AND SIGNATORIE** a list of countries will appear, select United Kingdom.



3. Look for the accredited body. And the result is "United Kingdom Accreditation Service (UKAS)"

4. Visit the website of UKAS and look for the Certifying Body (BSI) that is accredited for ISO 13485.

5. Look for the search bar and write the standard of the certificate “13485”, it will appear all the accredited certified bodies issuing this standard.



This flowchart can simplify the verification process: