



Ref. 2022-MDGUD-Q1-003

**Practicing without Medical Devices licensing
Corrective Action Guideline**

National Health Regulatory Authority (NHRA)

Kingdom of Bahrain

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Version 1.0



1. Introduction

With reference to Circular No. 39 of 2020 issued by the National Health Regulatory Authority which state that all medical devices importers and suppliers having the following Commercial registration activity “Sale / Trade in other machinery and equipment and parts-medical devices, supplies and related spare parts”.

Should obtain NHRA Authorized representative registration certificate before the 31st of December 2022, and based on Resolution No. 48 of 2020, Clause No. 6 issued by the Supreme Council of Health and as per the previously shared circular issued by the National Health Regulatory Authority with regard to medical devices local manufactures registration in NHRA before the 31st of December 2022 a violation will be recorded on the commercial registration of un-licensed medical devices companies and manufactures from NHRA.

2. Removing Violation

In order to remove the recorded violation, one of the following should be done:

For medical devices companies:

- Register in NHRA as an Authorize representative for medical devices.
- The activity of Sale/Trade in other machinery and equipment and parts - Medical Devices, Supplies and Related Spare Parts is canceled from the commercial registration, **please note that this option is available only for those companies who are not practicing the activity and an evidence of that must be provided to NHRA.**

For medical devices manufactures:

- Register in NHRA as a local manufacturer for medical devices.
- The activity of manufacturing medical devices is canceled from the commercial registration, **please note that this option is available only for those manufactures who are not practicing the activity and an evidence of that must be provided to NHRA.**



The authority would like also to point out that based of Article 4 of Decree-Law No. 21 of 2015 for health care facilities regarding the conduct of its activities within the limits of the license issued to it, it is un accepted to practice the activity of trading medical devices on the same commercial address of the HCF, therefore one of the following should be followed as it suits CR holder:

1. The activity of medical devices sale/trade is canceled from the commercial registration and treat further importation applications as personal use shipment for the facility only and not for business purposes.
2. Keep the commercial registration for medical devices trading and register in NHRA as an authorize representative for medical devices while transfer the CR to another address than the address of the HCF