nhra BAHRAIN
الهيئة الوطنية لتنظيم المهن والخدمات الصحية
NATIONAL HEALTH REGULATORY AUTHORITY

مملكة البحرين
Kingdom of Bahrain

مكتب الرئيس التنفيذي
Chief Executive Office

Date: 15Th March 2026

Circular No.: (5) 2026

To: All Medical Device and Medical Supply Manufacturers, Authorized Representatives, Wholesalers and Other Exporters Placing Products on the Bahraini Market.

Subject: Introduction of the NHRA Medical Devices & Supplies Traceability Programme

The National Health Regulatory Authority (NHRA) hereby informs all stakeholders that the Authority will introduce a national traceability programme for medical devices and medical supplies placed on the Bahraini market.

The initial phase of the programme will focus on manufacturers, authorized representatives, wholesalers and other exporters placing medical devices or medical supplies on the Bahraini market. These stakeholders represent the primary entry point for medical products into the national supply chain and are therefore the first participants required to engage with the traceability framework.

This initiative is part of NHRA's ongoing efforts to strengthen regulatory oversight, product monitoring and patient safety and to align Bahrain's regulatory framework with international best practices for medical product traceability and post market surveillance.

Regulatory Basis

This programme is implemented pursuant to:

- Law No. (38) of 2009 establishing the National Health Regulatory Authority
- Resolution No. (48) of 2020 on Medical Devices and Products Quality Control
- Resolution No. (24) of 2021 Amending Resolution No. (20) of 2016 Regarding the Determination of Fee Categories for Private Healthcare Institutions

These regulatory resolutions authorize NHRA to implement mechanisms necessary to monitor medical devices and products placed on the market in the Kingdom of Bahrain.

Programme Overview

The NHRA Medical Devices and Supplies Traceability Programme will introduce a digital regulatory platform designed to enable enhanced monitoring of medical devices and medical supplies throughout the supply chain.

The programme supports:

- enhanced regulatory visibility of medical products distributed in Bahrain
- strengthened post market surveillance
- improved product traceability and recall management

The participation of additional in-country supply chain stakeholders, including healthcare institutions and other local economic operators that do not fall under the definition of manufacturers, will be progressively incorporated into the programme in later implementation phases. Further guidance regarding these phases will be issued by NHRA in due course.

Phased Implementation

The implementation of the programme will follow a phased approach.

Key milestones are as follows:

April 2026

Opening of mandatory registration for Authorized Representatives, manufacturers, wholesalers and other exporters placing medical devices or medical supplies on the Bahraini market.

July 2026

Planned launch of the NHRA Medical Devices and Supplies Traceability Platform and commencement of regulatory requirements associated with the programme.

Additional information regarding registration procedures and technical onboarding will be communicated through subsequent circulars.

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Industry Support

NHRA recognizes the importance of maintaining continuous availability of medical devices and medical supplies within the Kingdom of Bahrain.

The Authority will therefore provide guidance and support to stakeholders during the onboarding phase to facilitate compliance with the programme while ensuring uninterrupted supply to healthcare institutions.

All relevant stakeholders are requested to monitor further NHRA communications regarding this initiative.

For inquiries, please contact: Medical_Devices@nhra.bh.

Thank you for your cooperation.

Dr. Ahmed Mohammed Al Ansari
Chief Executive Officer