

Medical Devices and Supplies Fee Schedule

This schedule updates the fees and charging rules in Annex 1 to Circular No. 15 of 2026.

All amounts are in Bahraini dinars (BHD).

Table 1 Medical Devices Authorized Representative Licensing Services

Service Type	Item	Type	Fees	Norm
Authorized Representative license application			50	Each new application
Authorized Representative licensing	Class A	First license	1,000	First license
		License renewal	700	Annual
	Class B	First license	700	First license
		License renewal	500	Annual
	Class C	First license	500	First license
		License renewal	300	Annual
	Class D	First license	300	First license
		License renewal	200	Annual
Medical devices warehouse licensing			1,000	First license
			800	Annual
Medical devices manufacturer licensing			5,000	First license
			3,000	Annual
Variation to a registered facility license or document			50	Each request
Re-inspection of medical device facilities			50	Each request

Authorized Representative Classes A to D are establishment categories, not IVD risk classes.

Table 2 Medical Device Registration Services

Service Type	Item	Type	Fees	Norm
Initial registration application			5	Each application
Initial SKU traceability charge			5	Each unique SKU or catalogue entry, subject to the shared 275-SKU charging limit
Medical device registration	Low risk	Initial registration/renewal	150	Each license
	Medium risk	Initial registration/renewal	300	Each license
	High risk	Initial registration/renewal	1,000	Each license
Medical Device Registration Variation (Update of Registered Information or Documents)			20	Each variation

Table 3 Medical Devices Importation Services

Service Type	Item	Type	Fees	Norm
Request approval to import a single device	Medical device	Registered	0.5	Each type
		Unregistered	2	Each type
	IVD / combined medical device	Registered	1	Each type
		Unregistered	3	Each type
Verify the validity of the quality certificate			5	Each type
Product classification request		Regular / Reliance	20	Each type
		Fast Track	40	Each type
Sample examination			5	Each type
Inspect the shipment at the port			10	Each type

Table 4 Other Services

Service Type	Item	Fees	Norm
Permit to use	Submit a request for approval to use a device	0.5	Each device
	Evaluate product viability	50	Each device
Certificates and official documents for medical device manufacturers and devices, including free sale and classification certificates		10	Each request
Supervise product disposal		25	Each request

Registration charging rules

Eligible range and linked applications

The product range must meet the grouping and approved-scope criteria in the Medical Devices Registration Guideline. The initial event consists of its linked first-registration applications. A common manufacturer, brand or invoice alone does not establish one eligible range. The applicant must identify linked applications. Unrelated ranges retain separate SKU charging limits.

IVD and Procedure Pack applications are limited to 50 separate SKUs or catalogue entries each. Other eligible application types have no numerical item limit. Each Reliance license must be supported by one accepted reference certificate.

Shared SKU charging limit

Charge no more than 275 unique SKUs for the same eligible product range and initial registration event. The maximum SKU traceability charge is BHD 1,375. Each unique SKU is charged once, in whole BHD 5 units.

Required split applications share the 275-SKU charging limit for the same eligible range and initial registration event. A split does not restart the limit. Initial application and license fees remain payable in full for each required application and license. No overall monetary ceiling applies to the total registration fees.

Deduct payments already collected under each charge category when calculating the balance due for the linked event. Do not charge the same unique SKU again within that event.

Every SKU remains individually registered, listed and traceable. Entries above the charging limit incur no further initial SKU traceability charge; they are not removed from the application or license scope.

Renewals and changes

The initial SKU charge is not reapplied merely because a license is renewed. Renewal and variation charges remain payable under the applicable service row. The shared SKU charging limit applies to initial registration.

Standard licenses are valid for three years. Reliance licenses expire after three years or with the accepted reference certificate, whichever is earlier. The fee does not guarantee a three-year Reliance term.

Risk groups and registration examples

Fee group	EU MDR	EU IVDR	Legacy EU evidence
Low	I, Is, Im, Ir	A	MDD I non-sterile; MDD I sterile; IVDD General or Other
Medium	Ila, Iib	B, C	MDD Ila or Iib; IVDD List B
High	III	D	MDD III; IVDD List A

Use NHRA's confirmed fee classification for other schemes or subtypes. Catalogue monitoring tiers do not replace the license fee classification.

Maximum for one application

Risk group	License	275 charged SKUs Total	50 charged SKUs Total
Low	150	1,530	405
Medium	300	1,680	555
High	1,000	2,380	1,255

Totals include the BHD 5 application charge.

Examples of linked initial registrations

Eligible range	Calculation	Payable
250 Medium risk size variants in one application	5 + 1,250 + 300	1,555
600 entries in one Medium risk range requiring two licenses	10 + 1,375 + 600	1,985
120 Medium risk IVD entries in three applications	15 + 600 + 900	1,515
250 High risk IVD entries in five applications	25 + 1,250 + 5,000 = 6,275	6,275

Examples assume accepted grouping, risk classification, reference scope and intended use.

Determine the required applications and licenses before applying the shared SKU charging limit.

The 275-SKU charging limit applies only to the initial SKU traceability charge in Table 2. It does not reduce application or license fees, or charges for establishment licensing, importation, classification, permit-to-use or other separate services.

Payment and application of charges

If NHRA rejects an application after the third submission, a new application subject to initial application fees is required.

Payment alone does not satisfy registration, import or traceability requirements. A limited traceability exemption does not waive registration or other charges.

Purchase and marketing prices submitted to NHRA are confidential regulatory information. A price-only change does not require a registration variation.

Other charges

Product classification assessment is charged under Table 3. Certificate issuance is a separate service under Table 4, subject to the certificate-fee decision.

Fast Track in Table 3 refers to product classification.

Registration service tracks follow the Medical Devices Registration Guideline.

This schedule introduces no additional premium or platform subscription charge beyond the fees expressly stated.

Commencement

This schedule takes effect on 15 October 2026. The new initial-registration charging provisions apply only to new applications submitted on or after that date. Earlier initial-registration applications retain the previous charging provisions, including outstanding charges. No retrospective recalculation or refund arises from these amendments. Treatment of pending requests for other revised services and linked applications spanning commencement requires confirmation.

Basis and related guidance

Resolution No. 24 of 2021, amending Resolution No. 20 of 2016; Circular No. 15 of 2026 and its Annex 1.

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