

Amendment to Medical Device Labeling Regulation — Turkish Language IFU and Electronic IFU QR Code Requirements

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1. Background

TITCK has identified inconsistent implementation of Turkish-language labeling requirements and conflicting interpretation of electronic Instructions for Use (e-IFU) carrier placement obligations across manufacturers operating in the Turkish market. This amendment clarifies and tightens both requirements to ensure patient safety and regulatory consistency.

2. Turkish-Language IFU — Mandatory from 01 October 2026

All medical devices placed on the Turkish market on or after 01 October 2026 must include a Turkish-language Instructions for Use. Acceptable formats are:

- (a) Printed Turkish IFU included with the device packaging; or
- (b) Electronic IFU system (e-IFU) meeting the requirements of Article 5 of this amendment.

Devices already placed on the market before 01 October 2026 may continue to be distributed until existing stock is exhausted.

3. Electronic IFU — QR Code Placement Requirement

The e-IFU QR code must appear directly on the primary device label or on a label permanently affixed to the device itself. Placement of the QR code solely on outer packaging without appearance on the primary label is no longer compliant from 01 October 2026. The QR code must resolve to a stable URL hosting the current Turkish-language IFU in PDF or HTML format.

Figure 1 — Example Conforming Primary Label Layout

PRIMARY DEVICE LABEL — Example Conforming Layout	
Device Name: [Product Name] Rev. X	
Manufacturer: [Company Name], [Address], Turkey / Türkiye	
Catalogue No: [REF] Lot: [LOT] MFG: YYYY-MM-DD	
e-IFU: [QR CODE HERE — must be on primary label from 01 Oct 2026]	
TR-MF-XXXX CE XXXX UDI: [UDI-DI]+[UDI-PI]	
Kullanma Talimatı / Instructions for Use: [URL or QR]	

4. Transition Provisions

Manufacturers currently operating e-IFU systems must submit a Labeling Change Notification to their Turkish authorised representative. The authorised representative must file a Type IA variation with TITCK. The Type IA variation fee is waived for changes made solely to comply with this amendment, provided the variation is submitted before 31 December 2026.

5. Enforcement

TITCK market surveillance activities from 01 October 2026 will include verification of QR code placement on primary device labels. Non-compliant products identified in market surveillance may be subject to withdrawal from market and administrative sanctions under Article 23 of the Medical Device Regulation.