


# BOGA & ASSOCIATES

## NEWSLETTER

*To keep you up to date with the latest legal and economic developments, this newsletter prepared by our Team provides information that may affect the operation of your business in Albania.*



*“On determining the specific conditions of licensing, accompanying documentation, review procedures, validity, suspension procedures and license revocation for manufacturers and wholesalers of medical devices in the Republic of Albania”*

**Decision: “On determining the specific conditions of licensing, accompanying documentation, review procedures, validity, suspension procedures and license revocation for manufacturers and wholesalers of medical devices in the Republic of Albania”**

The Council of Ministers has lately approved the Decision No. 227, dated 13.04.2022 **“On determining the specific conditions of licensing, accompanying documentation, review procedures, validity, suspension procedures and license revocation for manufacturers and wholesalers of medical devices in the Republic of Albania”** (the “Decision”).

The Decision provides a detailed regulatory framework on the specific licensing requirements pertaining to relevant medical devices, which must be fulfilled by manufacturers and wholesalers of medical devices.

The procedure for obtaining a license in both cases begins with the filing of a request along with the supporting documents at the service counter of the National Business Center.

The request file for the manufacturing license is examined by the Ministry of Health and Social Protection (the Ministry), through the Commission for Verification of the Conditions of Manufacturing of Medical Devices (the Commission).

The Commission within a period of 25 (twenty-five) days conducts the verification of the manufacturing conditions. After this deadline, the Commission recommends within 5 (five) days to the Minister of Health and Social Protection (the Minister) to grant or reject the approval act for the manufacturing of medical devices.

On the other hand, requests for a license for wholesale trade of medical devices and accompanying documentation are examined by the unit responsible for medical devices in the Ministry. This unit conducts the verification on the fulfillment of wholesale trade conditions through physical

inspection within 25 (twenty-five) days and afterwards within 5 (five) days gives a recommendation to the Minister regarding the issuance or not of the approval act for the wholesale trade of medical devices.

The decisions of the Minister are then published in the National Register of Licenses, Authorizations and Permits within 30 (thirty) days.

The Decision stipulates, *inter alia*, that licenses for the manufacturing and wholesale trade of medical devices are granted for indefinite term. In the meantime, authorizations for the wholesale trade of medical devices issued before the entry into force of this Decision are valid until the end of their validity period.





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If you wish to know more on issues highlighted in this edition, you may approach your usual contact at our firm or the following:

[info@bogalaw.com](mailto:info@bogalaw.com)

#### Tirana Office

40/3 Ibrahim Rugova Str.  
1019 Tirana  
Albania

Tel +355 4 225 1050

Fax +355 4 225 1055

[www.bogalaw.com](http://www.bogalaw.com)

[www.bogalawip.com](http://www.bogalawip.com)

#### Pristina Office

50/3 Sylejman Vokshi Str.  
10000 Pristina  
Kosovo

Tel +383 38 223 152

Fax +383 38 223 153

[www.bogalaw.com](http://www.bogalaw.com)

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**IFLR1000 2022:** Ranked **Tier 1** in Financial and Corporate

**Chambers Global 2022:** Ranked **Band 1** in Corporate/Commercial

**Chambers Europe 2022:** Ranked **Band 1** in 3 practice areas

**The Legal 500 2022:** Ranked **Tier 1** in Legal Market Overview

**Benchmark Litigation Europe 2022:** Top Ranked in Dispute Resolution

**WTR1000 2022:** Top Ranked in Trademarks

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The firm's particularity is linked to the multidisciplinary services it provides to its clients, through an uncompromising commitment to excellence. Apart from the widely consolidated legal practice, the firm offers the highest standards of expertise in tax and accounting services, with keen sensitivity to the rapid changes in the Albanian and Kosovo business environment. The firm delivers services to leading clients in major industries, banks and financial institutions, as well as to companies engaged in insurance, construction, energy and utilities, entertainment and media, mining, oil and gas, professional services, real estate, technology, telecommunications, tourism, transport, infrastructure and consumer goods.