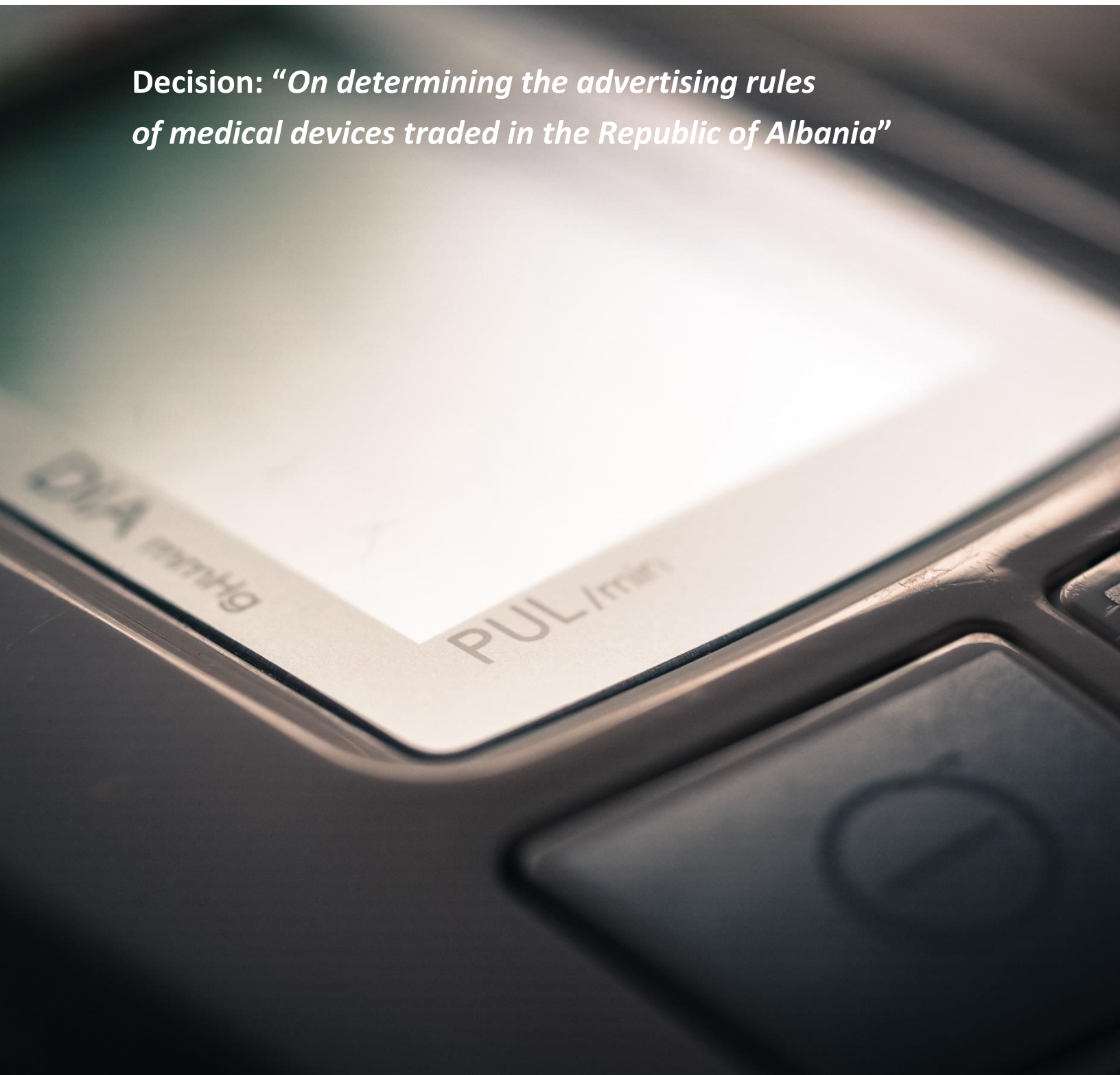


# BOGA & ASSOCIATES

## 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.*

**Decision: “On determining the advertising rules of medical devices traded in the Republic of Albania”**



## Decision: “On determining the advertising rules of medical devices traded in the Republic of Albania”

The Council of Ministers adopted the Decision no. 479, dated 13.07.2022 “On determining the advertising rules of medical devices traded in the Republic of Albania” (the “**Decision**”).

This Decision sets out basic rules regarding the advertising and promotion of medical devices.

Advertising of medical devices includes any activity that promotes the sale or use of a medical device in any written or verbal form whether electronic, digital or other, using pictures and sound, which can only be conducted by manufacturers and wholesale traders of medical devices as well as representatives of foreign manufacturers registered with the Albanian Commercial Register.

On the other hand, medical devices intended for use by health professionals i.e., doctors, dentists, pharmacists, veterinarians, nutritionists, etc. are exclusively advertised by the latter.

Medical devices are promoted in accordance with their intended purpose, declared by the manufacturer and by enabling sufficient information, which encompasses elements such as benefits, risks of treatment, costs and reimbursement.

Advertising of medical devices demonstrates the fulfillment of the requirements relating to CE marking or FDA certification. Hence, affixing of misinformative/deceptive signs on the intended use of the device that conflicts the CE marking or FDA certification or reduces their appearance and legibility, is forbidden.

Further, comparative advertising must clearly identify the medical devices that are being compared. A comparison is only permitted to be used as part of an advertisement if the following are compared:

- Devices covering products intended for the same use; and
- One or more core, verifiable and representative characteristics of medical devices, including their price.

As a general rule, advertising that does not meet the conditions defined by the legislation in force and this Decision is prohibited. However, this is not applicable to medical devices intended to be used in exhibitions, demonstrations, fairs or in other activities of this nature. These devices must be accompanied with a visible and clear sign indicating that they cannot be traded or put into use.

Finally, violation of the advertising rules constitutes an administrative offense and is subject to fines by the medical devices inspectors. The authenticity and safety of advertisement of medical devices is also monitored by the Ministry of Health and Social Protection.





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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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**BOGA & ASSOCIATES  
AWARDS AND RECOGNITION 2022**

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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.