

Medical devices in Bulgaria: Regulatory framework, market dynamics, and institutional development

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Abstract

Bulgaria occupies a unique position among European Union member states, with the lowest per capita healthcare expenditure (€990 annually) yet demonstrating the second-highest growth rate in health spending between 2014 and 2022. This economic paradox reflects the dynamics of a developing market operating under resource constraints while facing growing needs from an aging population. The medical devices sector is an essential component of Bulgaria's healthcare system, including products ranging from simple consumables to sophisticated implantable devices and advanced diagnostic equipment. This review examines the Bulgarian medical device landscape through multiple dimensions: historical evolution from medieval surgical instruments to contemporary AI-integrated systems, fundamental distinctions from pharmaceuticals and dietary supplements based on mechanisms of action, the comprehensive regulatory framework under Medical Device Regulation (MDR) 2017/745, institutional interactions among key organizations (the Bulgarian Drug Agency, the National Health Insurance Fund, the Ministry of Health), and market trends shaped by demographic transformation. With a population of 6.44 million (23.8% over 65 years), Bulgaria faces pressing demographic challenges that reshape healthcare demand patterns. The analysis reveals a market exceeding €300 million, dependent on imports (>90%), with limited domestic manufacturing capacity. Despite the financial constraints, Bulgaria has achieved an international recognition through top-tier regulatory inspections and active participation in the European regulatory structures. The review outlines perspectives for short-term priorities (2025–2027), medium-term objectives (2027–2030), and long-term vision (2030+) for sector development, emphasizing the digital transformation, regional coverage improvement, and demographic crisis management through the technological innovation.

Keywords

Medical devices, regulatory framework, Bulgaria, healthcare system, market analysis, MDR, demographic aging, reimbursement

Introduction

Medical devices are an essential component of modern healthcare systems, including a broad spectrum of products from simple medical consumables such as sterile

dressings and gauze to complex implantable devices including pacemakers and cardiac valves, as well as sophisticated diagnostic imaging equipment and laboratory analyzers (Akila et al. 2025). The global medical device industry has evolved from medieval surgical instruments to

contemporary AI-integrated systems, representing technological advancement that transforms healthcare delivery (Berchovich and Javitt 2018; Fraser et al. 2025).

In the Bulgarian context, this sector is particularly important due to specific demographic and economic challenges. The aging population, with a median age of 47.1 years and 23.8% of citizens over 65 years, generates increasing demand for specialized products, while limited financial resources necessitate careful selection and rational allocation of funds (NSI 2022a; NSI 2025). Bulgaria's healthcare expenditure of €990 per capita annually represents the lowest in the European Union, yet the country has demonstrated the second-highest increase in health spending between 2014 and 2023, following Romania (Eurostat 2025a). This economic paradox demonstrates the dynamics of a developing market operating under resource constraints with rising needs from the aging population.

The medical device market shows the high import dependency and actively seeks a balance between modernization needs and the limited financial capacity. The market shows structural vulnerability due to the complete reliance on imported high-technology medical equipment (>90% of market value), creating exposure to currency fluctuations, changes in the customs regimes, and international supply chain disruptions, as evidenced during the COVID-19 pandemic (U.S. International Trade Administration 2024). This review examines medical devices through several key dimensions: historical development from medieval origins to contemporary high-technology systems; the fundamental distinctions from pharmaceuticals and dietary supplements based on the mechanisms of action and the regulatory differences; an analysis of the contemporary regulatory framework including the transition to the new European regulations; an exploration of the institutional environment and inter-institutional interactions among the key organizations; an evaluation of the market trends, and perspectives for sector development in the coming decades.

Historical development and evolution

The Medieval Foundations – the historical roots of medical devices trace back to the ancient civilizations, but a systematic descriptions first appear in the medieval sources. Arab physicians of this period represented the vanguard of medical science. The most influential figure was al-Zahrawi (936–1013 CE), whose monumental 30-volume work „Al-Tasrif“ (Kitab al-Tasrif) described over 200 surgical instruments used in his practice (Amr and Tbakhi 2007). This medical „encyclopedia“ was the first systematic description of surgical instruments and techniques for their use. Al-Zahrawi's innovations established the grounds for the modern surgical practice through the development of specialized instruments for cataract surgery enabling delicate eye operations previously extremely risky or impossible, the creation and refinement of obstetrical

forceps substantially reducing the risks during complicated deliveries for both mother and child, and instruments for dental surgery revolutionizing tooth extractions and dental problem treatment. This systematic approach to the medical instrument development and documentation created traditions that profoundly influenced the medical technology development in the subsequent centuries (Kirkup 1995).

The European Renaissance (14th–16th centuries) inherited and developed the Arab medical knowledge, bringing revolutionary changes to the medical practice. This period of renewed interest in anatomical studies and empirical observation stimulated the need for more precise and specialized medical instruments. Andreas Vesalius's (1514–1564) anatomical investigations presented in „De Humani Corporis Fabrica“ (1543) stimulated the development of precise surgical instruments (Toledo-Pereyra 2008).

Ambroise Paré (1510–1590), known as the „father of modern surgery,“ developed innovative prostheses for amputated limbs markedly improving the quality of life for disabled individuals (Hernigou 2013a; Hernigou 2013b). The period witnessed the appearance of the first reading glasses in Italy during the 13th century, initially simple magnifying lenses mounted in frames (Cashell 1971). Their refinement in Holland during the 16th century, where high-quality glassmaking developed, established the foundations for modern optical medical technology.

The Age of Enlightenment (17th–18th centuries) led to systematization of medical knowledge and standardization of instruments. Antonie van Leeuwenhoek (1632–1723) perfected the microscope, achieving magnifications allowing observation of microorganisms for the first time in history (Kutschera 2023). French and German master craftsmen began specializing in medical instrument production, creating the first professional medical technology workshops.

The Industrial Revolution (late 18th–19th centuries) transformed the medical device production from manual craftsmanship to mass production. Metallurgy and mechanical engineering developments created possibilities for producing high-quality steel instruments in large quantities. The steel instruments from Sheffield, England, where world-renowned high-quality metalworking traditions developed, became the world standards for quality and reliability (Kirkup 1995; Kwan 2008). The discovery of anesthesia in 1846 revolutionized surgery, enabling longer and more complex operations, creating a need for more diverse and specialized instrumentation (Robinson and Toledo 2012). The Joseph Lister's introduction of antiseptics in 1865 created strict requirements for sterility and quality of medical instruments (Contractor et al. 2024).

Contemporary Development – the 20th century brought an exponential technological advancement, transforming medical devices from mechanical instruments to complex electronic and computerized systems. Introduction of the

electromedical equipment enabled new types of diagnosis and therapy previously impossible. The X-ray systems became integral to clinical practice in the first half of the 20th century, allowing non-invasive visualization of internal organs and bone structures (Berchovich and Javitt 2018). Implantable devices that could replace or support various organ functions were developed. The first pacemakers from the 1950s evolved from large external devices to the contemporary miniature implantable systems with long-term autonomy (Aquilina 2006).

The technological advancement in the recent decades has led to a significant proliferation in complexity and diversity of medical devices. The contemporary medical devices range from simple mechanical devices to complex implantable systems with integrated artificial intelligence, remote management and monitoring capabilities (Akila et al. 2025). Parallel to the technological evolution, the regulatory architecture has grown increasingly complex. In Europe, virtually no regulation existed until the fourth quarter of 20th century, gradually established at national level, then transitioned to supranational level with the emergence of the common European market. Currently, the legal regulatory frame consists of the unified European regulations for medical devices (MDR) (EUR-Lex 2017a) and in vitro diagnostic devices (IVDR) (EUR-Lex 2017b), creating the strictest regulatory framework globally (Fraser et al. 2025).

Distinguishing medical devices from other therapeutic products

Mechanisms of action as a defining factor

Understanding medical devices as a distinct therapeutic category begins with a clear definition of their fundamental mechanism of action. This distinction is not merely a formal administrative requirement but reflects the fundamental differences in how products interact with the human body and achieve therapeutic effects. The medical devices achieve their primary intended purpose through physical, mechanical, or physicochemical mechanisms, distinguishing them from pharmaceuticals that act through pharmacological, metabolic, or immunological mechanisms (FDA 2017).

Specific examples clarify this distinction. A compression stocking as a Class I medical device achieves therapeutic effect in venous insufficiency by creating an external pressure gradient, mechanically supporting the venous circulation (Diadiun et al. 2021). The stocking releases no chemical substances and does not biochemically affect the blood vessels. Its effect is purely physical and ceases immediately upon removal. In contrast, a venoactive pharmaceutical like diosmin acts through a biochemical strengthening of the vascular walls, a reduction of capillary permeability, and an anti-inflammatory action at molecular level. Its effect continues days after the ingestion and requires hepatic metabolism (Kakkos et al. 2023).

This distinction is not merely academic – it determines the entire approach to the product development, testing, and regulatory oversight. While the pharmaceuticals must demonstrate complex pharmacokinetic and pharmacodynamic properties including absorption, distribution, metabolism, and elimination, the medical devices are evaluated according to their ability to achieve predictable physical effects with minimal systemic impacts (Frigerio 2016). Clinical trials of pharmaceuticals require a detailed monitoring of the active substance concentrations and metabolites in the blood, while medical device trials focus on the functional outcomes and biomechanical parameters.

Risk-based classification system

A defining characteristic that distinguishes medical devices from all other healthcare products is the risk-based classification system. Unlike pharmaceuticals, dietary supplements, or cosmetics, medical devices are categorized into hierarchical classes based on the potential risk to patients, creating a regulatory regime that graduates oversight proportionally to the danger (MDCG 2021). Given the range of products from simple consumables to life-critical implants, this framework tailors its legal requirements to the specific risk profile of each device category. The European regulatory model establishes four risk-based categories. Classification depends on multiple factors including contact duration with the body, degree of invasiveness, whether the device is active or passive, and whether it is intended for vital anatomical areas such as the central nervous system or the cardiovascular system. This multifactorial assessment creates a nuanced system that accurately reflects the actual patient risk rather than applying uniform requirements to inherently different products.

Class I includes the lowest-risk devices such as compression stockings for venous thrombosis prophylaxis, sterile dressings, and plaster splints. These devices typically have a temporary body contact and do not penetrate the skin. The manufacturers can self-declare the conformity without a notified body participation, enabling market access within 3–6 months after completing the technical documentation. Class IIa includes devices with a moderate short-term risk such as contact lenses, hearing aids, and short-term infusion catheters. Class IIb includes high-risk or prolonged-contact devices including external automatic defibrillators, surgical lasers, and infusion pumps. Class III represents the highest potential risk devices including implantable defibrillators, cardiac valves, coronary stents, hip prostheses, and knee implants (EUR-Lex 2017a).

This risk-based stratification creates significantly different regulatory pathways and timelines. The class IIb and III devices require a mandatory notified body participation, clinical trials, and a detailed risk assessment, potentially taking 2–3 years for a market authorization (Fraser et al. 2025). The temporal difference between the lowest and the highest risk classes can exceed 30 months, reflecting the fundamental principle that the regulatory burden should correspond to the potential for patient

harm. No other healthcare product category employs such a sophisticated risk stratification – the pharmaceuticals follow uniform approval pathways regardless of the therapeutic area, while the dietary supplements face minimal premarket requirements across all product types.

The risk-based classification system represents a regulatory innovation specific to medical devices, acknowledging that a sterile gauze pad and an implantable cardioverter-defibrillator, while both classified as medical devices, require fundamentally different levels of regulatory scrutiny. This proportional approach balances patient safety with innovation accessibility, ensuring that low-risk products reach patients quickly while high-risk devices undergo a more rigorous evaluation. This characteristic regulatory architecture distinguishes medical devices from all other product categories in healthcare and beyond.

Comparison with pharmaceuticals

When comparing the medical devices with the pharmaceutical products, the regulatory and the temporal differences become pronounced. New pharmaceutical products require on average 10–15 years from the initial active substance discovery to the final market approval. This period includes preclinical studies, three phases of clinical trials with increasing participant numbers, and a detailed regulatory assessment of all safety and efficacy aspects. The pharmaceuticals follow this uniform pathway regardless of their therapeutic class or risk profile – the analgesic and an oncology drugs traverse identical regulatory phases, differing only in specific trial designs (Fraser et al. 2025).

This uniformity contrasts sharply with the medical device risk-based approach. A Class I compression stocking reaches the market in months through a self-certification, while a Class III implantable device requires years of clinical validation. The pharmaceutical model assumes that all drugs carry an inherent systemic risk requiring a comprehensive evaluation, whereas the medical device model acknowledges that a tongue depressor and a pacemaker present entirely different risk profiles warranting a proportional regulatory investment.

The comparison between the therapeutic approaches illustrates mechanism-based differences. For example transcutaneous electrical nerve stimulation (TENS) devices activate gate control mechanisms through electrical stimulation of A-beta nerve fibers, which have diameters of 6–12 micrometers and conduction velocities of 35–75 m/s. These fast myelinated fibers transmit tactile and vibratory sensations and, when activated, inhibit pain signal transmission from slow C-fibers in the substantia gelatinosa of the spinal cord dorsal horn.

In comparison, non-steroidal anti-inflammatory drugs (NSAIDs) achieve analgesic effect through cyclooxygenase-2 enzyme inhibition, reducing prostaglandin synthesis. Prostaglandins are the key mediators of inflammation and pain, sensitizing peripheral nociceptors and lowering the pain stimulation threshold. Their inhibition leads to a reduced inflammatory response and a direct analgesic

action. The NSAID mechanism is systemic; even when applied topically as a gel or an ointment, substantial active substance absorption occurs with systemic action.

The clinical results show TENS provides pain reduction with adverse effects in only 2–3% of patients, primarily local skin redness and irritation in electrode areas (Lewis et al. 1994). In comparison, NSAIDs demonstrate similar or slightly higher effectiveness for acute and chronic pain, but with gastrointestinal adverse effects in 10–30% of patients during a prolonged use (Raj et al. 2016). These adverse effects range from a mild dyspepsia and nausea to serious complications including gastric and duodenal ulcers, bleeding, and perforation, especially in the elderly patients and those with risk factors. From a pharmacoeconomic perspective, TENS devices represent a single investment usable repeatedly for months or years, while NSAIDs require continuous purchasing. For chronic pain requiring a prolonged therapy, cumulative NSAID costs can substantially exceed TENS device costs. Additionally, avoiding systemic adverse effects prevents the additional medical costs for complication management.

Comparison with dietary supplements

The competition between the medical devices and dietary supplements manifests in specific therapeutic areas where different mechanisms lead to different clinical profiles and regulatory requirements. This boundary is particularly blurred in prevention and maintenance of normal physiological functions, where both product categories claim benefits.

For joint diseases, compression knee braces as Class I medical devices provide measurable and objectively demonstrable biomechanical effects (Sharif et al. 2017). They improve proprioception through increased tactile information from the joint area, leading to a better neuromuscular control and joint stabilization. The compression reduces oscillations during stepping and improves postural stability. Clinical studies demonstrate statistically notable improvement in WOMAC scales assessing pain, stiffness, and functional limitations with daily compression knee brace use in the gonarthrosis patients (Bryk et al. 2011). In comparison, dietary supplements with glucosamine and chondroitin show inconsistent results in clinical trials, representing small and clinically questionable effects (Roman-Blas et al. 2017; Čeh and Šarabon 2023). Meta-analyses of multiple randomized controlled trials demonstrate substantial heterogeneity in the results, suggesting the effect is highly dependent on individual factors. Genetic polymorphisms in enzymes involved in the collagen metabolism explain why some patients report improvement while others do not. The baseline joint cartilage condition also influences response to these supplements substantially.

The regulatory requirements for medical devices and supplements differ substantially. The medical device labeling contains specific medical claims supported by clinical evidence, such as „reduces joint pain in osteoarthritis“ or „improves knee stability.“ These claims require a

documentation through clinical trials and scientific publications demonstrating a statistically notable effect compared to control or placebo. The medical device manufacturers bear responsibility for the validity of these claims and face sanctions for lacking supporting evidence. In contrast, the dietary supplements are strictly limited to general health claims without specific therapeutic pretensions. They claim to „support normal joint function“ or „contribute to maintaining healthy cartilage,“ which are general functional claims, but cannot claim to „treat arthritis“ or „reduce pain,“ which would be therapeutic claims requiring a drug registration. This regulatory difference is vitally important for consumers, as the level of evidence required to support claims is radically different.

Contemporary regulatory framework in Bulgaria

European regulation MDR – fundamental framework

The Bulgarian regulatory architecture for medical devices is built upon the European legislative framework, which applies directly in all EU member states. On May 26, 2021, Regulation (EU) 2017/745 (MDR) and 2017/746 (IVDR) were implemented, creating a unified European regulatory system applied directly in all 27 member states including Bulgaria without the need for national transposition (EUR-Lex 2017a; EUR-Lex 2017b). This means that MDR and IVDR have a direct effect and automatically supersede the conflicting provisions in the national legislation.

National legal foundations

Parallel to the direct MDR application, Bulgaria maintains its own national legislation, regulating the aspects not fully harmonized at European level or the items requiring specific national implementation. The primary national normative act is the Medical Devices Act, adopted June 12, 2007 (Republic of Bulgaria 2007). The law entered into force simultaneously with Bulgarian accession to the European Union on January 1, 2007 and initially represented transposition of European directives preceding MDR. After MDR entered into force in 2021, the Bulgarian law continues to operate in the parts not contradicting the regulation, regulating nationally-specific issues such as designation of competent authority, procedures for national-level market surveillance, administrative sanctions, the system for reimbursing medical devices from the public health insurance fund, and other management aspects falling within national authority competence.

The legal framework is supported and detailed by three key subordinate normative acts. Ordinance No. 7 of March 31, 2021 regulates the list of medical devices that can be paid with public funds through the National Health Insurance Fund (NHIF), creating legal basis for the electronic database of these devices (Republic of Bulgaria Ministry

of Health 2021). Ordinance No. 25 of November 10, 2008 regulates emergency cases where medical devices can be put into service under special circumstances related to life-threatening situations or health conditions when alternatives with valid CE marking are lacking (Republic of Bulgaria Ministry of Health 2008a). Ordinance No. 22 of October 14, 2008 regulates procedures for established problems with medical device safety or effectiveness, including requirements for manufacturers and wholesalers to maintain documented systems for safety tracking, corrective action mechanisms, and obligations for product market withdrawal when necessary (Republic of Bulgaria Ministry of Health 2008b).

Institutional environment: Registration, control, and reimbursement

The Bulgarian Drug Agency (BDA) plays a central role in medical device regulation, exercising regulatory oversight parallel to its competencies in pharmaceutical products. The agency functions as institutional successor to the National Institute for Medicinal Products, established in 1999 as the first specialized structure for regulatory oversight in the health sector following transition to democracy and market economy.

BDA operational activity in the medical devices segment has been increased after 2020 (BDA 2020; BDA 2021; BDA 2022; BDA 2023; BDA 2024). Between 2020 and 2024, the agency processed an average of 59 applications for registration annually, issued approximately 52 registration certificates per year, and received between 564 and 2,313 notifications for market placement. The dramatic peak of 2,313 notifications in 2021 represented a 2.6-fold increase compared to 2020, reflecting combined effects of the COVID-19 pandemic and mass notification submission before expiration of the transitional period under Directive 93/42/EEC. The subsequent sharp decline to 566 notifications in 2022 (-75.5%) and stabilization around 564–763 notifications in 2023–2024 signal a fundamental change in the regulatory regime.

This change relates directly to the full application of Regulation (EU) 2017/745 from May 26, 2021, which introduces a mandatory registration of economic operators in the EUDAMED European database before placing devices on market. Confirmed EUDAMED registrations demonstrate a gradual system entry: 82 registrations in 2022, 27 – in 2023, and 18 – in 2024, with post-initial-peak reduction reflecting the completion of the process for larger market players and more selective device placement under stricter requirements.

Parallel to the notification reduction, the post-market surveillance system shows a dramatic growth. Incident reports increased 6.5-fold from 23 in 2020 to 149 in 2024, reflecting not increased incidents but rather strengthened vigilance system and stricter economic operator obligations under Article 87 of Regulation (EU) 2017/745 for

immediate serious incident reporting. The notable increase in corrective action reports from 120 in 2020 to 214 in 2023 (followed by slight decrease to 194 in 2024) also illustrates an increased manufacturer proactivity in risk management, stimulated by strict sanctioning regimes and mandatory EUDAMED transparency.

BDA manages the electronic medical devices database, publicly accessible at meddev.bda.bg, representing a key instrument for sector transparency and accountability (BDA 2026). The database contains information for all medical devices payable with public funds, currently exceeding 137,000 products including implants, anesthesia and respiration products, in vitro diagnostic materials, and laboratory devices. The system provides access to prices and technical specifications for the Ministry of Health, NHIF, the Ministry of Labor and Social Policy, and hospitals purchasing medical devices, thereby reducing price speculation possibilities.

BDA experts actively participate in working groups and commissions for negotiating medical devices initiated by the National Health Insurance Fund, the Ministry of Health, the National Center for Transfusion Hematology, and the National Center for Infectious and Parasitic Diseases. Internationally, BDA maintains an active participation in multiple European structures, including training courses for national experts for joint notified body assessment, monthly participation in the „Joint Scientific Consultations“ subgroup of the Health Technology Assessment Co-ordination Group created by Regulation (EU) 2021/2282 (EUR-Lex 2021), and in meetings of the Medical Device Coordination Group (MDCG) held five times annually.

Fund The National Health Insurance Fund (NHIF) represents the central payer in Bulgaria's healthcare system, applying a complex system for medical device reimbursement that differentiates financing mechanisms according to care level. This system has evolved gradually since the fund's creation in 1999, reflecting accumulated experience from different financing and cost control methods. Prerequisites for including medical devices in the NHIF reimbursement lists are their conformity with MDR requirements, including a valid CE marking.

Hospital medical care is financed by NHIF through 267 clinical pathways including practically all diagnoses except psychiatric diseases. Clinical pathways represent standardized diagnostic-therapeutic algorithms describing all medical activities necessary for treating a specific disease or condition. Each clinical pathway has a predetermined price that NHIF pays to the healthcare facility for the entire complex of activities. However, the clinical pathway system is subject to scrutiny due to significant limitations when used as the primary financing instrument. Standardized prices often inadequately reflect the actual clinical complexity and resource intensity of individual cases, especially for patients with multiple comorbidities (Vekov et al. 2009).

Medical devices in hospital care are financed through three different mechanisms depending on the risk class,

value, and clinical application. The first mechanism covers lower-value medical devices integrated into standard clinical pathway prices. These devices include routine consumables such as dressing materials, syringes, infusion systems, and other basic medical materials necessary for standard treatment. Payment for these devices is automatically included in the total sum NHIF transfers to healthcare facilities for the respective clinical pathway, without requiring separate accounting for each device used.

The second mechanism covers specific medical devices from the list under Article 13, paragraph 2, point 2, letter „b“ of Ordinance No. 10 of 2009, which NHIF pays in full for the specific medical indications without an additional patient copayment. The third mechanism applies to high-value medical devices paid outside standard clinical pathway prices according to the list defined under Article 13, paragraph 2, point 2, letter „a“ of Ordinance No. 10 of 2009. The list categorizes medical devices by therapeutic group, with corresponding reference values determined for each. NHIF reimbursement is capped at these reference values, with any amount exceeding the threshold remaining the responsibility of the provider or patient. The groups include cardiovascular devices, orthopedic devices, ophthalmological devices, urological devices, and neurosurgical devices.

Medical device reimbursement in the outpatient medical care functions on the reference pricing principle, regulated in Ordinance No. 7 of March 31, 2021. Medical devices are organized into therapeutic groups according to the clinical applications and functional characteristics, with a reference value determined for each group representing the maximum sum NHIF pays. This model creates economic incentives for choosing products with an optimal price-quality ratio. Patients pay the full difference between reference price and actual price of chosen product if the latter exceeds reference value.

The procedures for annual negotiation of medical device prices and payment conditions include multi-stage mechanisms with manufacturers' and authorized wholesalers' participation. The assessment methodology considers multiple criteria including the offered price, clinical evidence base for product efficacy and safety, supply chain reliability, availability of after-sales service and technical support, and warranty conditions. NHIF publishes on its website the lists of all admitted procedure participants, proposed prices for respective medical device groups, and negotiation schedules. This publicity and transparency allows healthcare facilities, patient organizations, and general public to monitor the process and signal potential irregularities, creating effective mechanisms for public control over the public fund expenditure for medical devices.

Health technology assessment and reimbursement

Bulgaria's health technology assessment (HTA) system has undergone significant development over the past two decades, though still lagging compared to the developed

Western European countries (Benisheva-Dimitrova et al. 2017). The legal framework for HTA was established with Ordinance No. 9 of December 1, 2015 on conditions and procedures for conducting health technology assessment, which introduced mandatory assessment for medicinal products with new international non-proprietary names. The ordinance was repealed on April 1, 2019, with HTA functions transferred to the National Council on Pricing and Reimbursement of Medicinal Products according to Article 259, paragraph 1 of the Medicinal Products in Human Medicine Act.

Bulgaria does not have a formalized mandatory procedure for health technology assessment specifically for medical devices. The decisions for including medical devices in the NHIF reimbursement lists and price determination are made through negotiation mechanisms between NHIF, manufacturers, and authorized wholesalers within annual procedures. Inter-institutional working groups participate in these decisions, with representation from the Bulgarian Drug Agency, the National Health Insurance Fund, clinical experts, and academic specialists. Assessment includes consideration of clinical effectiveness, safety, offered prices, and budget impact, but does not follow formalized HTA protocols as with medicinal products (Iskrov and Stefanov 2015). The system for providing experts to working groups requires balancing clinical expertise, methodological skills, and absence of conflicts of interest.

In the international literature, the HTA process for medical devices has specific methodological challenges compared to pharmaceutical products (Daubner-Bendes et al. 2021). Clinical evidence for medical devices often comes from observational studies, registries, and real-world data, unlike randomized controlled trials that are the gold standard for medicinal product assessment. Medical devices evolve rapidly with incremental technological improvements, complicating long-term value assessment and creating challenges when comparing different device generations. Regional co-operation among Central and Eastern European countries in medical device HTA is recommended as a mechanism for sharing resources and expertise (Daubner-Bendes et al. 2021). Use of artificial intelligence and AI-based evidence in health technology assessment represents a new frontier in methodology, with recommendations to overcome barriers to using AI-generated evidence through developing new methodological guidelines and training HTA experts in algorithmic result interpretation.

Market analysis and statistical data

Market size and dynamics

The Bulgarian medical device market displays a unique paradox: while it records the lowest per capita expenditure on medical technology in the EU, it simultaneously exhibits the highest relative growth. This trend reflects

an intensive modernization effort and a steady alignment with European standards for healthcare infrastructure. The market size, according to Statista analyses, is expected to exceed €300 million in 2025 (Statista 2024). Leading consulting company's forecasts predict stable average annual growth of approximately 5.03% for the 2025–2029 period. This growth rate, though moderate in absolute numbers, is significantly higher than the average European growth, reflecting a potential for a catch-up development based on modernization infrastructure investments and growing population awareness of preventive healthcare.

This positions the Bulgarian market as one of the smallest in absolute values within the European Union, comparable in size to markets of other Eastern European states such as Croatia, Slovenia, and Baltic countries, but simultaneously as one of the most dynamically developing with substantial growth potential. According to detailed analyses by the U.S. International Trade Administration, which regularly surveys opportunities for American companies in various markets, Bulgaria's health sector shows significant potential for sustainable growth, especially in high-technology medical technology areas such as diagnostic imaging, minimally invasive surgery, and digital health solutions (U.S. International Trade Administration 2024).

The market structure shows a dominance of imported products, representing over 90% of the total value of medical devices used in Bulgaria. The domestic production is severely limited and concentrated primarily in simple consumables categories such as dressings, bandages, and sterile materials. Lack of domestic production of high-technology medical equipment creates a complete import dependence, making the market vulnerable to currency fluctuations, changes in customs regimes, and international supply chain crises, as observed during the COVID-19 pandemic.

Demographic determinants and health-care demand

Bulgaria's demographic structure undergoes radical transformations with long-term consequences for the health-care system and the medical devices market. According to official National Statistical Institute (NSI) data, total population reached 6,447,710 as of end-2022 (NSI 2022a). The negative demographic dynamics continued in subsequent years, with population decreasing to 6,445,481 at end-2023 and further to 6,437,360 at end-2024 (NSI 2025). This represents a sharp reduction compared to previous decades, reflecting one of contemporary Europe's most serious demographic crises, caused by a combination of low birth rates, high mortality, and intensive emigration of predominantly young and educated people.

The total population reduction with a corresponding shrinkage of potential consumer base creates a paradoxical situation for the medical devices market. While the absolute consumer numbers decrease quantitatively, which suggests a reduced overall market volume, the remaining population's qualitative profile transforms toward a higher-inten-

sity medical device usage, ultimately compensating for and exceeding the effect of the demographic shrinkage. This occurs because of a dramatic change in the population age structure, where the relative share and the absolute number of high-risk age groups continuously increase.

The intensive population aging reaches high levels, with 23.8% of the total population (1,544,245 persons) aged over 65 years at end-2024 compared to 23.5% in 2022 (NSI 2025). This makes Bulgaria one of the most aged nations not only in Europe but worldwide, with an elderly population share that continues to increase each year (Eurostat 2025b). This age group has a multiple-fold higher consumption of medical products compared to the younger groups. According to international statistics, persons over 65 generate 5–7 times higher healthcare expenditures and correspondingly higher medical device expenses compared to the average adults (Eurostat 2025a). The absolute number of more than 1.5 million persons over 65 represents an enormous and continuously growing medical devices market segment.

The geographic differentiation of age structure shows a clear distinction between different settlement types, reflecting complex migration processes and urbanization. Rural areas demonstrate a significantly higher elderly population concentration at 28.3% over 65 years compared to 21.8% in the cities. This geographic unevenness forms specific market characteristics in different regions. The rural areas, despite the smaller absolute populations, represent markets with a specific demand for certain medical device categories – primarily mobility aids, chronic disease management products, and home care devices. The high elderly population concentration in these regions generates a sustained demand for such products, but access is complicated by multiple factors including limited or absent public transport, distance from administrative centers, and poorly developed commercial infrastructure.

Healthcare system and infrastructure

Bulgaria's healthcare infrastructure includes 341 hospital facilities with over 54,707 hospital beds in 2022-multi-profile hospitals for active treatment, specialized hospitals by various medical specialties such as oncology, cardiology and orthopedics, and rehabilitation centers (NSI 2022b). The hospital network is concentrated in large urban centers, especially Sofia, Plovdiv, Varna, Pleven, and Burgas. These over 54,000 hospital beds represent an enormous institutional market for medical devices, with annual consumption varying substantially according to the department profile – from approximately €2,000–3,000 per bed in the general therapeutic departments to over €50,000 per bed in the intensive care units.

The healthcare system staff structure includes over 29,000 physicians, representing 45.9 physicians per 10,000 population, and approximately 28,827 nurses, corresponding to roughly 46.6 nurses per 10,000 population (Dimova et al. 2018). While these figures appear acceptable in comparison to some European counterparts, they

mask significant underlying issues. One of the most serious structural problems remains the acute shortage of approximately 30,000 nurses necessary to ensure the optimal care level according to European standards.

The nursing shortage creates tension in the healthcare system and stimulates compensatory mechanisms. Automated patient monitoring devices, intelligent infusion pumps with automatic regulation, remote monitoring and alarm systems, and various assistive devices reducing the staff's physical burden are becoming increasingly sought in the context of a personnel deficit. This phenomenon accelerates the hospital infrastructure technological renewal and stimulates the implementation of more modern and effective medical devices.

Bulgaria's position in the European context

Bulgaria occupies a strategically important but challenging position in the European healthcare system with per capita health expenditures below the European average of €3,685, creating one of the largest financial inequalities within the European Union (Eurostat 2025a). The 7.7:1 ratio between the highest expenditures in Luxembourg, reaching €6,590 annually per resident, and the lowest expenditures in Romania (€858) and Bulgaria (€990), illustrates deep structural inequalities in the European healthcare directly affecting contemporary medical technology accessibility and overall healthcare service quality.

The out-of-pocket patient expenditures in Bulgaria reach 35.1% of the total health expenditures, representing a double and triple excess over EU average of 15.4%, creating substantial financial barriers to the necessary medical care access for most of the Bulgarian households, especially the socially vulnerable groups (Atanasova et al. 2013). The high out-of-pocket payments function as financial barriers and lead to a lower healthcare service utilization level, especially among the low-income households (Balabanova and McKee 2004). A research on Bulgarian consumers' preferences regarding quality, access, and price attributes of the healthcare services shows that the price is a decisive factor in the healthcare service choice, with patients willing to compromise quality or convenience to reduce personal expenditures (Van de Schoot et al. 2017).

While the absolute health spending remains low, Bulgaria recorded the highest per capita growth rate in the European Union between 2014 and 2022, with expenditures effectively doubling during this period. (Eurostat 2025a). This growth trend continues in 2023, when the total current health expenditures reach near 7.5 billions euro, representing 7.92% of GDP (NSI 2024). For the 2014–2023 period, Bulgaria registered the second-largest increase in total healthcare expenditures in the EU with 148.9% growth, surpassed only by Romania (155.6% growth) (Eurostat 2025a). This reflects both the growing population health awareness and the willingness to invest in prevention and early diagnosis, as well as the gradual approximation to the European healthcare financing standards.

The regulatory effectiveness and international recognition of Bulgarian health authorities show mixed but generally encouraging results. Bulgaria actively participates in European regulatory processes, including implementing the new Medical Devices Regulation and the EUDAMED system for electronic medical device data management, which will provide transparency and traceability. The Bulgarian Drug Agency receives an international recognition for its high professional standards and competence. The most prestigious recognition is the FDA approval for conducting GMP inspections with equivalent level to American standards, placing Bulgaria in the elite group of countries with mutually recognized regulatory systems and allowing the Bulgarian manufacturers to export directly to the American market without additional inspections (EMA 2019).

Perspectives

The short-term priorities (2025–2027) include a substantial increase in the public financing for medical devices through a targeted expansion of NHIF nomenclatures and inclusion of the new technological categories (Belichenova 2021). Achieving full alignment with EU regulatory platforms like EUDAMED is essential. This requires not only a technical integration but also an active participation in the European mutual recognition and coordination processes. To significantly improve regional coverage, it is essential to introduce mobile diagnostic units for remote areas and establish telemedicine links between tertiary centers and peripheral healthcare facilities. Public-private partnerships are a priority to ensure the access to advanced medical technologies without relying solely on public funding for high initial investments.

The medium-term objectives (2027–2030) encompass large-scale, coordinated digitalization investments, maximizing the use of European funding programs, including the Recovery and Resilience Facility (OECD 2023). Key initiatives include the creation of a unified national telemedicine platform, fully integrated across all healthcare levels. For rural areas, the development of comprehensive integrated care is envisioned through the deployment of portable diagnostic devices with remote interpretation capabilities and real-time specialized consultations.

The long-term vision (2030+) focuses on addressing the demographic crisis through a complex set of interrelated measures. These include the large-scale rollout of robotic systems for automated home and institutional care, the widespread implementation of AI in diagnostics – featuring autonomous decision-making for standardized clinical scenarios (Akila et al. 2025) and the establishment of fully integrated digital ecosystems for predictive chronic disease management. The ultimate goal is to reach EU averages for key health indicators such as accessibility, quality, and effectiveness while positioning Bulgaria as a regional hub for clinical research and medical innovation (Chamova 2017).

Conclusion

Medical devices in Bulgaria represent a dynamically evolving sector undergoing intensive transformation and modernization. The analysis reveals a complex market landscape that combines substantial challenges with promising growth prospects. Although Bulgaria has the lowest per capita health expenditure in the European Union and high levels of patient co-payments creating financial barriers to accessing contemporary medical technology, the country has also recorded the highest relative growth in health spending across the EU. Furthermore, Bulgaria is actively integrating into the European regulatory structures, including the full implementation of the stringent MDR (EU) 2017/745 framework. The institutional environment in Bulgaria is well-structured, with clearly distributed responsibilities among the Bulgarian Drug Agency – responsible for regulatory oversight and electronic database management, the National Health Insurance Fund managing the two-tier reimbursement model for hospital and outpatient care, and the Ministry of Health overseeing strategic management of the whole health sector. The recognition of the Bulgarian regulatory authority at an international level including FDA approval for the conduct of GMP inspections and active participation in the EUDAMED database demonstrates the high quality of the regulatory processes. The current demographic trends, characterized by an aging population (23.8% aged 65 and over) and a projected population decline to under five million by 2090, create specific challenges and opportunities for the medical devices sector. The growing need for chronic disease management products, rehabilitation devices, and home care systems is stimulating demand and creating the necessary conditions for a sustained market growth. Simultaneously, the deficit of medical personnel, particularly nurses, necessitates a broader implementation of automated and digital solutions to compensate for the shortage of human resources. The technological development of medical devices, from the simple mechanical instruments in the Middle Ages to the contemporary AI-integrated systems, reflects the sector's continuous evolution. Innovations such as adaptive CPAP machines with machine learning, AI-powered sleep apnea diagnostic systems, intelligent wearable cardiovascular monitors, and closed-loop diabetes management systems demonstrate how medical devices are transforming the healthcare paradigm from reactive to proactive and predictive medicine. The Bulgarian contribution through innovative solutions like Checkpoint Cardio, which serves over 70,000 patients across more than 50 European locations, proves that the country possesses the capacity to develop competitive medical technologies with a global impact.

While Bulgaria faces pressing medical device challenges related to the limited financial resources, the demographic crisis, and regional inequalities in healthcare access, the country possesses a solid regulatory foundation, an

actively developing industry, and a clear vision for health system modernization and digitalization. The successful implementation of the outlined measures would position Bulgaria as a regional hub for clinical research and medical innovation, providing Bulgarian patients with access to the most advanced medical technologies with an optimal quality, safety, and cost ratio.

Additional information

Conflict of interest

The authors have declared that no competing interests exist.

Ethical statements

The authors declared that no clinical trials were used in the present study.

The authors declared that no experiments on humans or human tissues were performed for the present study.

The authors declared that no informed consent was obtained from the humans, donors or donors' representatives participating in the study.

The authors declared that no experiments on animals were performed for the present study.

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- The authors declared that no commercially available immortalised human and animal cell lines were used in the present study.
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- ### Data availability
- All of the data that support the findings of this study are available in the main text.
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