B Lab Statement on BIOVITALIS Ltd's B Corp Certification
B Lab's independent Standards Advisory Council has rendered the following decision and guidance regarding eligibility for B Corp Certification for companies in the pharmaceutical industry:

"B Lab and its independent Standards Advisory Council have determined that pharmaceutical companies are eligible for B Corp Certification if they have not engaged in specific prohibited practices in the last five years AND are meeting additional industry specific practice requirements outlined below…"

BIOVITALIS Ltd is required to disclose a summary of how it complies with these industry requirements as a part of its B Corp Certification. For more information on the specific requirements, please refer to B Lab's position statement on Pharmaceutical Companies here.

Summary of Company
BIOVITALIS's activities focus on the development, production, and distribution of natural cosmetic products, dietary supplements, and related health support products. The company is not involved in the development or manufacture of prescription (RX) or over-the-counter (OTC) medicines.

The company undertakes internal formulation development, which represents its R&D function, particularly for cosmetics and food supplements based on natural ingredients. Manufacturing activities are carried out in Croatia. Distribution is managed through the company's own web shop, as well as pharmacies and specialized retail stores, indicating direct engagement with end consumers rather than institutional pharmaceutical markets.

BIOVITALIS has direct operations solely in the Republic of Croatia, where product development, manufacturing, and sales activities are centralized. Outside Croatia, the company operates indirectly through distribution partners. Within the European Union, its products are distributed in countries such as the Netherlands, Slovakia, Belgium, and Slovenia. Beyond the EU, BIOVITALIS products are sold in neighboring and regional markets including Bosnia and Herzegovina, Montenegro, and North Macedonia. The company does not maintain production facilities outside Croatia and does not rely on contracted manufacturing.

BIOVITALIS's product offerings are centered on preventive health, well-being, and natural care. Key areas of focus include cosmetics for sensitive and problematic skin, such as dry skin and skin prone to atopy, as well as products designed to support the immune system and general well-being. The portfolio also includes products tailored for children and families, alongside natural aromatherapy solutions.

Approximately 65% of the company's revenue is derived from cosmetic products, 28% from dietary supplements, and the remaining 7% from aromatherapy and related products.

BIOVITALIS Ltd's Disclosure on Prohibited Practices
Pharmaceutical companies engaged in the following practices in the last five years, as demonstrated through company disclosures or through material, justified, and unresolved stakeholder concerns, are currently ineligible for B Corp Certification:

- Companies engaged in any form of lobbying or policy advocacy that endanger consumer safety, promote an anti-competitive environment (e.g. by opposing increased transparency measures), inhibit affordable pricing, or limit equitable access to medicine. This includes membership, Board involvement, or funding of industry associations that engage in such lobbying activities.
- Companies utilizing intellectual property strategies for branded products to influence an unjustified delay to the introduction of an authorized generic product to the market (e.g. "evergreening" patents).
- Companies engaged in price gouging as evidenced by significant and unjustified year-over-year price increases to their products.

BIOVITALIS Ltd has been reviewed in accordance with B Corp Certification's Disclosure Questionnaire and background check requirements, including disclosure of its involvement in lobbying and advocacy activities, intellectual property strategies, and price changes in order to verify it is meeting the above requirements regarding prohibited industry practices. The company's approach to managing these material topics to the industry are further detailed below.

BIOVITALIS Ltd's Disclosure on Required Best Practices

1. *Adherence to credible national and/or international standards of safety, quality, and efficacy covering all relevant stages of the drug life cycle (i.e. drug development, supply chain, manufacturing, and distribution), which should include explicit systems to manage the risk of substandard medicines.*

BIOVITALIS applies structured quality and safety practices that are aligned with applicable regulatory expectations for health supplements. Product development is conducted internally, with a focus on formulation quality, ingredient selection, and compliance with relevant regulatory requirements.

Manufacturing and supply chain management for dietary supplements are centralized in Croatia, with no outsourced or third-country production. This concentrated production model reduces supply chain complexity and enhances oversight and control over raw materials and finished products. BIOVITALIS maintains internal quality control systems and full traceability of raw materials and product batches, enabling the identification, monitoring, and mitigation of risks related to substandard or non-compliant products.

Distribution of dietary supplements takes place through controlled channels, including pharmacies, specialty stores, and the company's own web shop, both domestically and through partners in selected EU and non-EU markets. Pricing practices are described as transparent and justified by production and regulatory costs, with adjustments made to reflect local purchasing power in lower-income markets. The absence of aggressive sales targets or quota-driven incentives further reduces the risk of inappropriate sales practices that could compromise product quality or consumer trust.

Because BIOVITALIS does not manufacture or distribute prescribed medicines/drugs, it does not face risks related to counterfeit or substandard pharmaceuticals. As such, formal systems for managing counterfeit medicines are not applicable. Nevertheless, the company's application of GMP-aligned manufacturing standards, regulatory compliance, batch traceability, and internal quality controls collectively function as effective safeguards against substandard cosmetic and supplement products.

2. *A Code of Ethics and/or other policies applicable to all company employees and critical third parties that establish minimum expectations with regard to anti-corruption and bribery, lobbying and advocacy activities, company interactions with healthcare professionals/organizations, and ethical marketing (where applicable). The company must also have clear processes to enforce the Code, including an accessible whistleblowing channel, and regular training of staff and third parties on the Code.*

BIOVITALIS has adopted an internal Code of Ethics that applies to all employees and extends to key business partners, which covers critical third parties involved in its operations. The Code is supported by specific internal policies, including an anti-corruption and anti-bribery policy, as well as ethical marketing rules. Together, these documents establish minimum standards of conduct and explicitly address risks related to improper influence, unethical business practices, and responsible market behavior.

In terms of lobbying and political activities, BIOVITALIS does not engage in lobbying or advocacy activities and does not finance political parties, campaigns, or interest groups. This non-engagement position reduces exposure to lobbying-related risks and provides clarity to employees and partners regarding acceptable conduct.

In terms of interactions with healthcare professionals and organizations, the company has clear internal guidelines governing cooperation with pharmacies and healthcare professionals. These guidelines are designed to ensure that such interactions are conducted ethically and transparently, without inducements or inappropriate incentives that could influence professional judgment.

Ethical marketing practices are addressed through internal marketing rules and a sales model that avoids aggressive or quota-driven incentives. The commission-based sales structure, combined with a fixed salary component, is designed to discourage overselling or pressure tactics, particularly in price-sensitive markets. This approach supports ethical promotion and responsible relationships with customers and healthcare-related distribution channels.

Regarding enforcement, BIOVITALIS has put in place several mechanisms:

- The Code of Ethics applies formally to employees and key partners, setting clear expectations for behavior.
- The company maintains an internal reporting (whistleblowing) channel through which irregularities or ethical concerns can be raised.
- Regular employee training is conducted to ensure awareness and understanding of ethical standards, policies, and acceptable conduct.

3. *Public disclosure detailing the company's approach to government affairs, inclusive of lobbying/advocacy and political activities. This should include disclosure of the material issues that the company lobbies/advocates for, their trade associations, and the controls they have in place in regards to political contributions, lobbying/advocacy on the company's behalf, revolving door policy, political contributions and donations.*

BIOVITALIS has internal policies such as its Code of Ethics and anti-corruption and anti-bribery policy that explicitly prohibit lobbying and political engagement on the company's behalf. These internal controls serve as preventive measures, ensuring that employees and key business partners do not undertake political contributions, lobbying, or advocacy activities in the company's name.

4. *For companies involved in research & development, public disclosure of its R&D and intellectual property strategies and disclosure of annual resources invested in both internal and collaborative R&D activities.*

BIOVITALIS is involved in limited, internal research and development, focused on formulation development for its dietary supplements and health support products. The company is not engaged in pharmaceutical drug discovery, clinical research, or large-scale collaborative R&D

programs. Its R&D activities are modest in scope and primarily aimed at ensuring product quality, safety, and incremental improvement rather than generating proprietary pharmaceutical breakthroughs.

BIOVITALIS does not use aggressive, exclusionary, or market-restrictive IP practices. Intellectual property is applied solely to protect product quality, formulations, and brand integrity, and not to limit competition or market access.

BIOVITALIS has disclosed that its R&D budget for 2025 is approximately EUR 7,000, which is allocated entirely to internal product development activities. The company does not engage in collaborative R&D with external partners, academic institutions, or research organizations, and therefore does not have collaborative R&D expenditures to disclose.

5. *For companies involved in research & development for priority diseases, conditions, and pathogens identified in the Access To Medicine Index, R&D processes for both internal and collaborative R&D activities must include a framework to develop equitable access plans for such projects. Access plans must be project-specific and include detailed commitments and strategies to improve access to such products in low- and middle- income countries (LMICs).*

BIOVITALIS is not involved in research and development for priority diseases, conditions, or pathogens as defined by the Access to Medicine Index. The company does not develop pharmaceutical medicines, vaccines, biologics, or other therapeutic products intended to diagnose, treat, cure, or prevent specific diseases. Its R&D activities are limited to internal formulation development for dietary supplements and general health support products, which are positioned for wellness and preventive support rather than for medical treatment of priority health conditions.

As a result, BIOVITALIS does not conduct R&D projects that require project-specific equitable access plans, nor does it engage in collaborative R&D activities that target unmet medical needs in low- and middle-income countries.

As BIOVITALIS does not develop products addressing priority diseases or conditions, it has not established formal R&D frameworks for equitable access planning, including commitments on pricing, licensing, technology transfer, or distribution strategies for LMICs tied to specific R&D projects. Any pricing adaptations the company applies in lower-income markets are commercial and market-access decisions for existing wellness products, rather than structured access plans linked to R&D for essential medicines.

6. *For companies involved in sales, public disclosure of its approach to pricing which, at a minimum, utilizes pricing instruments that are generally accepted by public health agencies*

to set prices in all markets (such as internal reference pricing, external reference pricing, and value-based pricing). Additionally, for sales in LMICs, pricing strategies must prioritize the payer's ability to pay across different segments of a country's population and aim to improve access to those in need.

Product prices are determined transparently, taking into account production costs, regulatory requirements, and affordability for end users. In doing so, BIOVITALIS applies elements of value-based pricing, particularly by emphasizing the natural origin, formulation quality, and pharmaceutical-grade standards of its products. Prices are positioned above low-cost generic wellness products but remain significantly lower than those of large international health and pharmaceutical brands, indicating an effort to balance perceived value with accessibility.

For lower- and middle-income markets, including Bosnia and Herzegovina, North Macedonia, and Montenegro, BIOVITALIS adapts its pricing strategy to local purchasing power. The company describes the use of penetration pricing mechanisms when entering these markets, such as lower introductory prices and promotional campaigns (e.g., bundled offers), to improve initial affordability and access. While maintaining its positioning as an "affordable premium" brand, BIOVITALIS explicitly considers price sensitivity and payer ability to pay in these markets.

7. *For companies involved in sales, companies have financial incentive structures for sales agents/teams designed to encourage responsible sales practices and minimize the risk of overselling (for example, by decoupling bonuses from sales volume).*

BIOVITALIS has implemented a financial incentive structure for its sales team that combines a fixed salary with a commission on sales, rather than relying on aggressive, quota-based bonus schemes. This structure is designed to encourage sustainable, ethical sales behavior and to minimize the risk of overselling, particularly in markets with lower purchasing power.

The company does not use fixed sales quotas or volume-driven bonus targets that could pressure sales staff to push excessive volumes of products into pharmacies or retail outlets. By avoiding bonuses tied to mandatory sales thresholds, BIOVITALIS reduces incentives that often lead to oversupply, stock expiration, or inappropriate pressure on customers and distribution partners.

8. *[IF APPLICABLE] In addition to the above requirements, companies listed on the Access To Medicine Index must also achieve a score of 2.50 or higher in each of the Index's three specific topic areas*

The Index's scoring requirements does not apply to the company as they do not develop, manufacture, or sell prescription or over-the-counter medicines, nor does it conduct R&D targeting priority diseases.

B Lab's Public Complaints Process

Any party may submit a complaint about a current B Corp through B Lab's Public Complaint Process. Grounds for complaint include:

1. Intentional misrepresentation of practices, policies, and/or claimed outcomes during the certification process, or
2. Breach of the core values articulated in our Declaration of Interdependence within the B Corp Community.