



To Whom It May Concern,

Company details

Vaion Health is a longevity company that aims to make NAD+ available to everyone. We are run by experienced executives, a team of consultant doctors and proven entrepreneurs. Through our new method of administering NAD+, we want to bring the benefits and longevity of NAD+ to broad spectrum of clients.

At Vaion Health we know that people's longevity isn't pre-determined and our Mission is to help them live the best and longest life possible by delivering NAD+ to customers in a safe, convenient and painless way. This way, anyone can reap the benefits of elevated NAD+ levels at home.

Product Overview

Nicotinamide adenine dinucleotide (NAD+) is a co-enzyme that is found in every cell of the human body and has been shown to delay cellular senescence (ageing), enhance cognitive abilities & lower the risk of many chronic diseases:

- 1. Boosting Metabolism:** NAD+ plays a significant role in metabolism, helping to convert nutrients into energy. Supplementing with NAD+ can potentially boost metabolic functions, which might be beneficial for those dealing with metabolic issues.
- 2. Improving Cellular Health:** NAD+ is essential for maintaining cellular health as it facilitates the repair of DNA and regulates cellular functions through signaling. By boosting NAD+ levels, it's possible to enhance cellular resilience and function.
- 3. Anti-Aging Effects:** Some research suggests that NAD+ can slow some aspects of the aging process. This is because it can improve the health and survival of cells, particularly in relation to mitochondrial function, which deteriorates with age.
- 4. Enhancing Brain Function:** NAD+ has been studied for its potential benefits in brain health. It may support cognitive function and combat neurological degeneration by providing neurons with the energy they need and by activating enzymes that protect against stress and DNA damage.
- 5. Supporting Heart Performance:** NAD+ might help improve cardiovascular performance by supporting the function of mitochondria in heart cells and reducing oxidative stress, which is a risk factor for heart disease.

Product range

This document covers all Vaion Health products under name **NAD+ by VAION**: the variations of pen & cartridges, various volumes & concentrations of IV drips and powder to be dissolved.



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Product regulatory status

References:

UK Department of Health "Food supplements", <http://www.dh.gov.uk/publications>

MHRA Guidance Note 8, "A guide to what is a medicinal product"

UK Food Supplements Regulations

EU Food Supplements Directive 2002/46/EC

Food Information to Consumers Regulation (FIC) (Regulation (EC) 1169/2011)

Nutrition and Health Claims Regulation (Regulation (EC) 1924/2006)

According to the **UK Food Supplements Regulations** and the **EU Food Supplements Directive 2002/46/EC**, a food supplement is defined as a concentrated source of a vitamin, mineral, or other substances with a nutritional or physiological effect. These supplements are intended to supplement the normal diet and are sold in dose form. Vaion's NAD+ fits within this definition as it is marketed for its physiological benefits related to energy and longevity without making medical claims.

Key Points Supporting Supplement Classification:

1. No Medicinal Claims:

- Vaion's product does not claim to treat, prevent, or cure any disease, which is a critical factor in determining its classification. According to the MHRA, a product is classified as a medicinal product if it is presented as having properties for treating or preventing disease or if it modifies physiological functions to a significant extent.
- The language used to describe Vaion's product as an "energy booster" and a "longevity product" aligns with acceptable claims for food supplements. These claims are focused on maintaining or supporting health rather than treating specific conditions, which falls under the scope of food law, not medicine.

2. Administration Context:

- While the product is administered via IV, which is less common for food supplements, the key determinant is the intent and presentation of the product. Since the product is not promoted with therapeutic claims, the administration method alone does not necessitate its classification as a medicine.
- The controlled administration by physicians in IV clinics ensures the product's safety but does not change its status as a food supplement, particularly if the product's use is consistent with the guidelines for supplements and not for therapeutic treatment.



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3. Ingredients and Safety:

- NAD+ is a naturally occurring molecule that plays a crucial role in cellular energy production. As long as the product is manufactured following food supplement regulations (including purity, dosage, and safety standards), it can be legally marketed as a food supplement.

4. Legislative References:

- Vaion product's classification aligns with the **Food Information to Consumers Regulation (FIC) (Regulation (EC) 1169/2011)** and the **Nutrition and Health Claims Regulation (Regulation (EC) 1924/2006)**, which govern the claims that can be made for food supplements. Since Vaion product's claims are related to general health maintenance, they do not cross into medicinal territory, thus not requiring a marketing authorization under medicinal product regulations.

Conclusion: Given the absence of medicinal claims, the adherence to food supplement regulations, and the intended use of your NAD+ IV vials as an energy and longevity supplement, it is justified to classify Vaion product as a food supplement rather than a medicinal product. This classification is consistent with both UK and EU regulations for food supplements.

See **Appendix 1** and **2** for further information.



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Appendix 1. Claim comparison.

Below are key points to justify that Vaion product is a food supplement that falls under the UK Food Safety Act and Food Supplements Regulations 2003:

No.	Point	Claim	
		Supplement /UK Food Safety Act and Food Supplements Regulations 2003/	Medicinal product /Medicines Act/
1	Legal definition	<input checked="" type="checkbox"/> A food product that is meant to supplement the normal diet.	<input type="checkbox"/> Presentation Criterion: it is presented as having properties for treating or preventing disease in human beings.
2		<input checked="" type="checkbox"/> A concentrated source of nutrients or other substances with a nutritional or physiological effect.	<input type="checkbox"/> Function Criterion: it is used or administered to human beings with a view to restoring, correcting, or modifying physiological functions by exerting a pharmacological, immunological, or metabolic action.
3	Purpose	<input checked="" type="checkbox"/> The primary purpose is to correct nutritional deficiencies, maintain an adequate intake of certain nutrients, or to support specific physiological functions. Not intended to treat or prevent diseases.	<input type="checkbox"/> Are primarily intended to be used with the aim of diagnosing, preventing, treating, or curing diseases. The emphasis is on pharmacological action or intervention in physiological processes to achieve a specific medical outcome.
4		<input checked="" type="checkbox"/> The focus is on supplementation for health maintenance or enhancement rather than disease management.	<input type="checkbox"/> Above includes anything that modifies or interacts with physiological processes in a way that helps combat specific health issues or diseases.
5	Marketing & labels	<input checked="" type="checkbox"/> Clearly marketed as a means to supplement diet, not presented as a remedy or treatment for diseases.	<input type="checkbox"/> Claims that suggest the product can prevent, treat, or cure human diseases.
6		<input checked="" type="checkbox"/> Labels clearly indicating, that the product is a food supplement.	<input type="checkbox"/> Labels indicating, that the product is a medicinal product.





Appendix 2. FAQ

1. Is the Product Safe?

Yes, the product is safe when used as directed. NAD+ is a naturally occurring molecule in the human body, playing a crucial role in cellular energy production. Vaion Health ensures that the product is manufactured in compliance with food supplement regulations, which include rigorous standards for purity, dosage, and safety. Additionally, stability testing and a Certificate of Analysis (COA) support its safety profile.

Vaion follows robust quality control of all raw materials, storage and final product, as well as full traceability. Following HACCP & ISO22000, both based on GMP requirements, ensures high level of quality of products. Stability testing and a Certificate of Analysis (COA) would further support its safety profile. Vaion's product is only shipped with passed sterility & endotoxin test results, prepared from raw materials of at least 99% purity, with acceptable levels of contaminants.

2. Is the Product a Pharmaceutical?

No, the product is not a pharmaceutical. According to the UK Food Supplements Regulations and the EU Food Supplements Directive 2002/46/EC, the product is classified as a food supplement. It does not make any medicinal claims such as treating, preventing, or curing diseases. The product is marketed as an energy booster and longevity supplement, which falls under the scope of food law rather than pharmaceutical regulation.

3. Does the Product Require a Doctor's Prescription?

No, the product does not require a doctor's prescription. As a food supplement, the product is available for use without the need for a prescription. However, it is administered by physicians in IV clinics, which ensures safe and controlled use, particularly because it is delivered intravenously.

4. Can a Lay User Buy IV Vials?

No, a lay user cannot buy IV vials directly. The product is designed for administration by healthcare professionals in a clinical setting. This controlled environment ensures that the product is used safely and effectively, and it is not intended for purchase or use by the general public without professional supervision.

5. Is the Product manufactured according to GMP (Good Manufacturing Practice) ?

Yes, the Product is manufactured according to GMP requirements incorporated in both HACCP and ISO22000 food standards. The compliance with food supplement regulations requires adherence to GMP standards to ensure the quality and safety of the product. However, the product is not a pharmaceutical and it does not require certified GMP manufacturing site, it requires following GMP rules.



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