Manufacturer's Declaration

Manufacturer:

Donnerstag trade s.r.o
Nademlejnská 600/1,
Praha 9 - Hloubětín 198 00

Company Registration Number: 02143097

Product:

ATGreen Oxygen

The manufacturer declares that the intended use of the product is to assist with fatigue, exhaustion, and stress. The product is not intended for diagnosing, treating, or preventing any disease. Therefore, according to Articel 1 Section 2, of DIRECTIVE 2001/83/EC, product is **not considered as a medicinal product**. Additionally, under Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, Article 2, it is **not classified as a medical device.**

The product is subject to Directive 2014/68/EU of the European Parliament and of the Council about harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment. As the product operates under low pressure and volume, it falls under the parameters of Article 4, Subsection 3 – meaning it is neither marked with the CE mark, nor does the manufacturer issue a declaration of conformity.

A safety data sheet for the product has been prepared in accordance with Directive (EU) 2015/830 and Regulation (EU) 1907/2006.

Date: 16.12.2024

Location: Praha

Signature: ...

Donnerstag trade s.r.o.
Nademlejnská 600/1
198 00 Praha 9 - Hloubětín
IČO: 02143097, DIČ: CZ02143097

Position: Company manager / Statutory

Resources:

DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 6 November 2001 on the Community code relating to medicinal products for human use

TITLE I DEFINITIONS Article 1

For the purposes of this Directive, the following terms shall bear the following meanings:

1. *Proprietary medicinal product: Any ready-prepared medicinal product placed on the market under a special name and in a special pack.*
2. *Medicinal product: Any substance or combination of substances presented for treating or preventing disease in human beings. Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product*

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices

Article 2

Definitions For the purposes of this Regulation, the following definitions apply:

(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes: — diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, — diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability, — investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, — providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means. The following products shall also be deemed to be medical devices: — devices for the control or support of conception; — products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

DIRECTIVE 2014/68/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 15 May 2014n the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment

Article 2

Definitions For the purposes of this Directive, the following definitions shall apply: (1) 'pressure equipment' means vessels, piping, safety accessories and pressure accessories, including, where applicable, elements attached to pressurised parts, such as flanges, nozzles, couplings, supports, lifting lugs; (2) 'vessel' means a housing designed and built to contain fluids under pressure including its direct attachments up to the coupling point connecting it to other equipment; a vessel may be composed of more than one chamber;

Article 4

Technical requirements

1. The following pressure equipment shall satisfy the essential safety requirements set out in Annex I:

(a) vessels, except those referred to in point (b), for:

(i) gases, liquefied gases, gases dissolved under pressure, vapours and also those liquids whose vapour pressure at the maximum allowable temperature is greater than 0,5 bar above normal atmospheric pressure (1 013 mbar) within the following limits:

— for fluids in Group 1 with a volume greater than 1 L and a product of PS and V greater than 25 bar·L, or with a pressure PS greater than 200 bar (Annex II, table 1),

— for fluids in Group 2, with a volume greater than 1 L and a product of PS and V is greater than 50 bar·L, or with a pressure PS greater than 1 000 bar, and all portable extinguishers and bottles for breathing apparatus (Annex II, table 2);

(ii) liquids having a vapour pressure at the maximum allowable temperature of not more than 0,5 bar above normal atmospheric pressure (1 013 mbar) within the following limits:

— for fluids in Group 1 with a volume greater than 1 L and a product of PS and V greater than 200 bar·L, or with a pressure PS greater than 500 bar (Annex II, table 3),

— for fluids in Group 2 with a pressure PS greater than 10 bar and a product of PS and V greater than 10 000 bar·L, or with a pressure PS greater than 1 000 bar (Annex II, table 4);

(b) fired or otherwise heated pressure equipment with the risk of overheating intended for generation of steam or superheated water at temperatures higher than 110 °C having a volume greater than 2 L, and all pressure cookers (Annex II, table 5);

(c) piping intended for:

(i) gases, liquefied gases, gases dissolved under pressure, vapours and those liquids whose vapour pressure at the maximum allowable temperature is greater than 0,5 bar above normal atmospheric pressure (1 013 mbar) within the following limits:

— for fluids in Group 1 with a DN greater than 25 (Annex II, table 6),

— for fluids in Group 2 with a DN greater than 32 and a product of PS and DN greater than 1 000 bar (Annex II, table 7);

(ii) liquids having a vapour pressure at the maximum allowable temperature of not more than 0,5 bar above normal atmospheric pressure (1 013 mbar) within the following limits:

— for fluids in Group 1 with a DN greater than 25 and a product of PS and DN greater than 2 000 bar (Annex II, table 8),

— for fluids in Group 2 with a PS greater than 10 bar, a DN greater than 200 and a product of PS and DN greater than 5 000 bar (Annex II, table 9).

(d) safety and pressure accessories intended for equipment covered by points (a), (b), and (c) including where such equipment is incorporated into an assembly.

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2. The following assemblies which include at least one item of pressure equipment covered by paragraph 1 shall satisfy the essential safety requirements set out in Annex I:

(a) assemblies intended for generating steam or superheated water at a temperature higher than 110 °C comprising at least one item of fired or otherwise heated pressure equipment presenting a risk of overheating;

(b) assemblies other than those referred to in point (a), if the manufacturer intends them to be made available on the market and put into service as assemblies.

By way of derogation from the first subparagraph, assemblies intended for generating warm water at temperatures not greater than 110 °C which are manually fed with solid fuels and have a PS·V greater than 50 bar·L shall comply with the essential safety requirements referred to in points 2.10, 2.11, 3.4, 5 (a) and 5 (d) of Annex I.

3. Pressure equipment and assemblies below or equal to the limits set out in points (a), (b) and (c) of paragraph 1 and in paragraph 2 respectively shall be designed and manufactured in accordance with the sound engineering practice of a Member State in order to ensure safe use. Pressure equipment and assemblies shall be accompanied by adequate instructions for use.

Without prejudice to other applicable Union harmonisation legislation providing for its affixing, such equipment or assemblies shall not bear the CE marking referred to in Article 18.