

AN AFFIDAVIT

replacing

Certificate of quality and origin of the goods, or declaration of conformity

Preamble:

This sworn declaration is issued by the registrar of the following product as an equivalent substitute for the Certificate of Quality and Origin of the Goods.

The document is issued as part of the electronic registration of new products in the PDK codebook. The PDK-UNIVERSUM codebook is a uniform codebook in particular of medicinal products, medical supplies and goods of a complementary nature, intended for sale in pharmacies, hospitals, medical facilities and stores of a similar type, including related information, documentation and other documents, for example this Declaration of Honor, by which the Registrar it confirms the necessary quality of its product.

I DECLARE

that the product manufactured/imported/distributed by us is of the type:

" DIETARY SUPPLEMENTS ".

The products of ZDRAVÁ TRÁVA s.r.o., identified below,
meet the following requirements:

Regulation (EC) No. 178/2002 of the European Parliament and of the Council establishing the general principles and requirements of food law, establishing the European Food Safety Authority and establishing procedures relating to food safety
Regulation of the European Parliament and the Council (EC) No. 852/2004 on food hygiene, as amended
Regulation 1019/2008/EC amending Annex II of the Regulation, Regulation (EC) No. 853/2004 of the European Parliament and of the Council on the hygiene of food of animal origin, as amended by Regulation 1020/2008/EC amending Annexes II and III ordinance
Commission Regulation No. 2073/2005/EC on microbiological criteria for food, as amended by Regulation 1441/2007/EC
Regulation 282/2008/EC on materials and articles made of recycled plastics intended for contact with foodstuffs and amending Regulation 2023/2006/EC
Regulation of the European Parliament and the Council (EC) No. 1924/2006 on data relating to food in terms of its nutritional value and effect on health. Regulation (EC) No 258/97 of the European Parliament and of the Council on novel foods and novel food ingredients
Regulation of the European Parliament and the Council (EC) No. 1925/2006 on the addition of vitamins and minerals and certain other substances to food.
Commission Regulation (EC) No. 1881/2006 establishing maximum limits for certain contaminating substances in food, as amended by Regulation 629/2008/EC.
Regulation of the European Parliament and the Council (EC) No. 396/2005 on the maximum limits of pesticide residues in food and feed of plant and animal origin and on their surface and amending Council Directive 91/414/EEC, as amended by Commission Regulation (EC) No. 178/2006, as amended by Regulation 149/2008/EC
Regulation (EC) No. 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors
Decision 2009/163/EC amending Decision 1999/217/EC as regards the list of flavoring substances used in or on foodstuffs (notified under number K (2009) 1222)
Directive 2008/128/EC laying down specific purity criteria for colors for use in foodstuffs
Directive 2008/84/EC establishing specific criteria for the purity of food additives other than colors and substitute sweeteners
Regulation 41/2009/EC on the composition and labeling of foods suitable for people with gluten intolerance
Regulation 1331/2008 establishing the authorization procedure for food additives, enzymes and flavoring substances
Regulation 1332/2008 on food enzymes
Regulation 1333/2008 on food additives
Regulation 1334/2008 on food substances intended for flavoring
Regulation 1243/2008/EC amending Annexes III and VI to Directive 2006/141/EC as regards the compositional requirements of certain infant formulas

Decision 2008/809/EC on non-inclusion of certain substances in Annex I, IA or IB of Directive 98/8/EC on placing biocidal products on the market.

Regulation 629/2008/EC, which amends Regulation 1881/2006/EC, which sets maximum limits for certain contaminating substances in foodstuffs OJ L 173, 07/03/2008, p. 6

Directive 2002/46 of the European Parliament and of the Council of 10 June 2002 on the harmonization of the laws of the Member States relating to food supplements

Regulation 665/2011/EU on the approval and non-approval of certain health claims in food labeling relating to the reduction of disease risk

Regulation 666/2011/EU on the non-approval of certain health claims in the labeling of foods that do not relate to the reduction of the risk of disease or the development and health of children Regulation (EU) No. 1169/2011 on the provision of information on food to consumers, amending the Regulation of the European Parliament and the Council (EC) No. 1924/2006 and (EC) No. 1925/2006 and on the repeal of Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, European Parliament and Council Directive 2000/13/EC, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No. 608/2004 (effective from 2014, nutrition labeling then 13 December 2016)

Commission Regulation (EU) No. 432/2012 of 16 May 2012 establishing a list of approved health claims for food labeling other than claims on the reduction of disease risk and on the development and health of children

Regulation of the European Parliament and the Council (EU) No. 1151/2012 of 21 November 2012 on quality regimes for agricultural products and foodstuffs.

Regulation of the European Parliament and of the Council (EU) No. 1308/2013 of 17 December 2013 establishing a common organization of markets in agricultural products and repealing Council Regulation (EEC) No. 922/72, (EEC) No. 234/79, (EC) No. 1037/2001 and (EC) No. 1234/2007.

Act No. 258/2000 Coll., on the protection of public health, as amended by Act No. 254/2001 Coll., Act No. 274/2001 Coll., Act No. 13/2002 Coll., Act No. 120/2002 Coll. and Act No. 274/2003 Coll., Act No. 356/2003 Coll. and Act 253/2005 Coll. and Act No. 381/2005 Coll. and Act No. 392/2005 Coll. and Act No. 444/2005 Coll. and Act No. 59/2006 Coll. and Act No. 222/2006 Coll., Act No. 264/2006 Coll., Act No. 342/2006 Coll., Act No. 110/2007 Coll., Act No. 296/2007 Coll., Act No. 378/2007 Coll., Act No. 124/2008 Coll., Act No. 130/2008 Coll., Act No. 274/2008 Coll., Act No. 41/2009 Coll., Act No. 227/2009 Coll., Act No. 281/2009 Coll. and Act No. 301/2009 Coll., Act No. 151/2011 Coll., Act No. 115/2012 Coll., as amended by Act No. 223/2013 Coll.

Regulation No. 471/2005 Coll., Full text of Act No. 258/2000 Coll., on the protection of public health, as amended by Act No. 254/2001 Coll., Act No. 274/2001 Coll., Act No. 13/2002 Coll., Act No. 120/2002 Coll. and Act No. 274/2003 Coll. disciple. No. 356/2003 Coll. and Act No. 392/2005 Coll.

Act No. 110/1997 Coll., on food and tobacco products, as amended by Act No. 119/2000 Coll., as amended by Act. No. 306/2000 Coll., as amended by Act No. 146/2002 Coll., as amended by Act. No. 316/2004 Coll. and Act No. 120/2008 Coll. and Act No. 139/2014 Coll.

Regulation No. 456/2004 Coll., Full version of Act No. 110/1997 Coll., on food Regulation No. 224/2008 Coll., Full version of Act No. 110/1997 Coll., on food and tobacco products and on amendment and supplementing some related laws.

Proclamation MZe No. 113/2005 Coll., on the method of labeling food and tobacco products, as amended by Proclamation No. 368/2005 Coll. and proclamation no. 497/2005 Coll. and published No. 101/2007 Coll. and published No. 127/2008 Coll.

Proclamation MZd No. 38/2001 Coll., on hygiene requirements for products intended for contact with food and dishes, as amended by Decree no. No. 186/2003 Coll., promulgation No. 551/2006 Coll., promulgation No. 271/2008 Coll., promulgation No. 386/2008 Coll., promulgation No. 127/2009 Coll., as amended by promulgation No. 111/2011 Coll.

Proclamation MZd No. 298/2012 Coll. on the cancellation of decree no. No. 235/2010 Coll., on setting requirements for purity and identification of additives, decree no. No. 319/2010 Coll. as amended No. 121/2011 Coll.

Proclamation MZd No. 158/2004 Coll., which sets the maximum permissible amount of residues of individual types of pesticides in food and in food raw materials, as amended by Proclamation No. 68/2005 Coll., as amended by Proclamation No. 400/2006 Coll.

Proclamation MZe No. 211/2004 Coll., on testing methods and methods of collection and preparation of control samples, as amended by Proclamation No. 611/2004 Coll., promulgation No. 238/2005 Coll. and proclamation no. 459/2005 Coll.

Proclamation MZd No. 304/2004 Coll., which establishes the types and conditions of use of additives and auxiliary substances in food production, as amended by decree no. No. 152/2005 Coll. and published No. 431/2005 Coll.

Proclamation MZd No. 305/2004 Coll., which determines the types of contaminating and toxicologically significant substances and their permissible amounts in food.

Proclamation MZd No. 343/2003 Coll., which issues a list of plants used for pharmaceutical and therapeutic purposes.

Decree of the Ministry of Health No. 225/2008 Coll., which establishes requirements for food supplements and food fortification with food supplements.

Legislative Decree No. 98/2005 Coll., establishing a rapid warning system for the emergence of a risk of health hazards from food and feed

Proclamation MZd No. 278/2010 Coll., which repeals Decree No. 381/2007 Coll., on setting maximum limits for pesticide residues in food and raw materials, as amended.

Proclamation MZd No. 277/2010 Coll., which repeals Decree of the Ministry of Health No. 273/2000 Coll., which establishes the maximum permissible residues of veterinary drugs and biologically active substances used in animal production in food and food raw materials, as amended.

Proclamation MZd No. 4/2008 Coll., which establishes the types and conditions of use of additives and extraction solvents in the production of food, decree no. No. 130/2010 Coll., as amended by promulgation No. 122/2011 Coll.

Proclamation MZe No. 227/2008 Coll., which sets the flat-rate amount of additional inspection costs, costs incurred to verify compliance with specifications and costs incurred by the competent authorities in connection with the entry or import of food and raw materials from third countries (decree on flat-rate costs).

Proclamation MZd No. 260/2012 Coll., on the repeal of Decree No. 447/2004 Coll., on requirements for the amount and types of substances intended for flavoring food, conditions of their use, requirements for their safety and conditions of use quinine and caffeine.

Proclamation MZd No. 299/2012 Coll., on the content of erucic acid in certain foods.

Government Decree No. 282/2014 Coll. on certain conditions for the implementation of the common organization of the market in the sector of milk and milk products.

Proclamation MZe No. 320/2014 Coll. on information obligations of the recipient of food at the destination in relation to certain types of food.

I declare that the dietary supplements produced, imported, distributed and marketed by me meet the requirements of Regulation (EC) No. 1169/2011 on the provision of information about food to consumers and the requirements of Act No. 110/1997 Coll. on foodstuffs as amended.

Various exceptions from the decrees (ingredients, not mentioned in the decree, exceeding limit values) are evaluated and assessed by the SZÚ, or SÚKL (e.g. limit values if it may be a new type of food).

I further declare that the food produced, imported, distributed and marketed by me does not contain anabolic steroids and steroids.

Food supplement - definition according to the law

A food supplement is a food whose purpose is to supplement a normal diet and which is a concentrated source of vitamins and minerals or other substances with a nutritional or physiological effect, contained in the food alone or in combination, intended for direct consumption in small measured quantities. Product effectiveness and quality assurance are not assessed when approving dietary supplements. However, the manufacturer may not declare false claims about the effect of the product (prohibition of misleading the consumer). He must be able to document the declared effects at any time. Dietary supplements must meet all applicable food standards. Their compliance is checked by the State Agricultural and Food Inspection (SZPI). Dietary supplements may not be marked with a medical indication on the packaging (nor may they indicate the cure or prevention of diseases), which is reserved only for medicines. However, beneficial effects on the health of the user may be stated - so-called health claims. The same applies to advertising. It must also not be stated or implied that a balanced and varied diet cannot provide sufficient nutrients.

In the event that we put food, dietary supplements and packaging on the market, I declare that it meets the requirements of Act No. 477/2001 Coll., on packaging, as amended by Act No. 274/2003 Coll., Act No. 94/2004 Coll., Act No. 237/2004 Coll., Act No. 257/2004 Coll., Act No. 444/2005 Coll., Act No. 66/2006 Coll., Act No. 296/2007 Coll., Act No. 25/2008 Coll., Act No. 126/2008 Coll., Act No. 227/2009 Coll., Act No. 281/2009 Coll., Act No. 77/2011 Coll., Act No. 18/2012 Coll. and Act No. 167/2012 Coll. and Act No. 62/2014 Coll., in particular §§ 3, 4, 5, 6, 14 and 15, as well as the implementing regulations of this Act, as far as they relate to packaging produced / imported by me.

List of registered products to which this declaration applies:

NEURON – CONCENTRATION with CBD - 60 CAPSULES

VITAMÍNE C 1000mg - 30 CAPSULES, VITAMÍNE C 1000mg with CBD - 30 CAPSULES

VITAMÍNE C 1000mg - 90 CAPSULES, VITAMÍNE C 1000mg with CBD - 90 CAPSULES

VITAMÍNE K+D3 - 30 CAPSULES, VITAMÍNE K+D3 with CBD - 30 CAPSULES

MULTIMINERAL MG - 30 CAPSULES, MULTIMINERAL MG with CBD - 30 CAPSULES,

JOINT NUTRITION - 30 CAPSULES, JOINT NUTRITION with CBD - 30 CAPSULES

JOINT NUTRITION - 90 CAPSULES, JOINT NUTRITION with CBD - 90 CAPSULES

FAT BURNER CLA 1000 mg - 30 CAPSULES, FAT BURNER with CBD - 30 CAPSULES

CBD ORTHO PHARMACEUTICAL GEL

Stamp and signature of the manufacturer/exporter/importer/distributor:

Name and signature of the authorized person, stamp, authorized person's signature and stamp.

RADEK PYTLÍK COMPANY EXECUTIVE



Place and date of issue, (place and date of issue.

In Těrlíck on March 1, 2023



ZDRAVÁ TRÁVA®

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Společnost zapsaná pod C 69343 / KSOS - Krajský soud v Ostravě