



GMP and HACCP

Through carefully selected suppliers with many years of experiences on pharmaceutical market and on the market with cosmetics, all ESSENS products can showcase their origin of the internationally recognized GMP certificate. Also all the suppliers are HACCP certificate holders.

Global markets, international production and supply of raw materials and active pharmaceutical ingredients increases the complexity of supply chains, that's why GMP audits guarantee the highest possible quality and unified global approach.

We bring you the informations, what is GMP and HACCP certificates are and what the certification entails.

GMP is english shortcut for Good Manufacture Practice.

It is a system, that aims to improve the safety of drugs, food, cosmetics, animal feed, etc.

GMP determines the rules of operation to avoid the danger (ex. the emergence of hazardous food) and that the legislation won't be violated.

After the compliance with strict rules and standards according to rules of international regulation the producer, grower or breeder receive the certificate, which is a necessary to renew regularly.

GMP certification works under the auspices of WHO World Health Organisation.

The reason of the creation was to ensure globally mostly harmless medications. Poor quality of the medicines doesn't only carries a health risks, but it is also a waste of funds and not only by the consumers, but also by national governments. Poor handling of drugs may contain toxic substances or on the contrary the therapeutic ingredients occurs in inadequate quantities, which does not required therapeutic effect. During the production process the quality must be built. A different stages of production are controlled. It is not enough to test the finished product. The aim is that the countries accept only the import and sale of the medicinal products, which have been manufactured in accordance with GMP.

The main risks of non - certified companies are:

- product contamination - it may cause in adverse health effect or even death
- incorrect labeling of packaging - the risk of misuse
- insufficient or too much active ingredient - ineffective action or side effects

The course and certification conditions of GMP:

- all aspects of the production are controlled - the used space , raw materials, education, personal hygiene of employees
- for individual processes are developed the necessary detailed written procedures, which may have some influence for the final product quality.
- for individual process of the production process must be documented proof of the correct procedure for each and every product
- WHO has established the detailed guidelines for GMP, which may be at each states different and which may be formulated in accordance of self requirements, but always in base of WHO GMP

HACCP is english shortcut for Hazard Analysis and Critical Control Points

It is a system for every food businesses producing, the processing and the food distribution.

The system is also for the enterprises, which come into the food chains (agriculture, manufacturers of packaging materials, etc.) The main objective of HACCP are the healthy foodstuffs. HACCP system's creation and implementation is a mandatory from the year 2004 and in base of Regulation of the European Parliament and of the Council. The requirements on HACCP system in Czech Republic is governed by bulletin of the Department of Agriculture CZ 2/2010.



SGS

Certificate TR22/81875350

The management system of

ERTE KOZMETİK SAN. TİC. A.Ş.

ÇİHANGİR MAH., GÜVERCİN CAD., NO: 5/1 C BLOK
AVCILAR, İSTANBUL, TURKEY

has been assessed and certified as meeting the requirements of

ISO 22716



Cosmetics – Guidelines on Good Manufacturing Practices (GMP)

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 12 January 2022 until 11 January 2025
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before
Issue 1. Certified since 12/01/2022

This is a multi-site certification.

Additional site details are listed on the subsequent page.

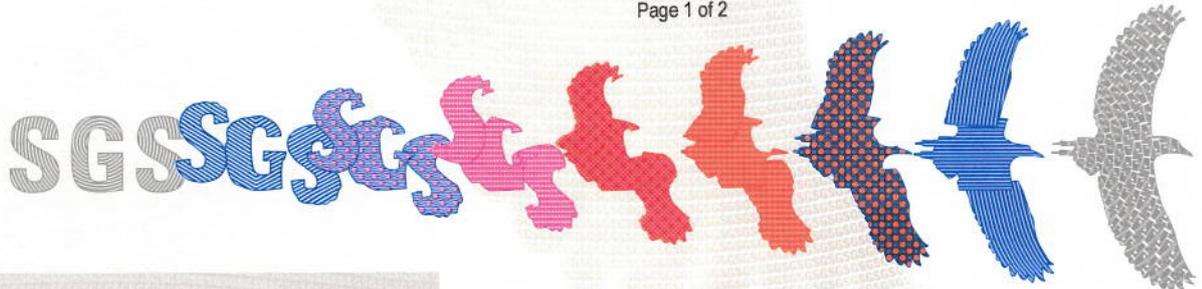
Authorised by

Pieter Weterings
Certification Manager

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ERTE KOZMETİK SAN. TİC. A.Ş.

ISO 22716



**Cosmetics – Guidelines on
Good Manufacturing Practices (GMP)**

Issue 1

Detailed scope

**Manufacturing of Perfumes and Fragrances Alcoholic, Manufacturing
of Body Care, Manufacturing of Bath Care, Manufacturing of Skin Care,
Manufacturing of Hair Care, Manufacturing of Sun Care**

Additional facilities

**CİHANGİR MAH., GÜVERCİN CAD., NO: 1 A BLOK
AVCILAR, İSTANBUL, TURKEY**



CERTIFICATE

Certification Body for certification of management systems
accredited by ČIA according to ČSN EN ISO/IEC 17021-1:2016

CERT QUALITY SYSTEM s.r.o.

certifying the Management Systems

confirms that the Company

K2pharm s.r.o.
Ratibořská 1651/177a, Kateřinky
CZ – 747 05 Opava

for fields of activities:

**Research, development and manufacturing of food
supplements.**
**Research, development and manufacturing of
cosmetics.**

has established and applies an Management Systems
in accordance with fulfilment

**general requirements for the system of critical points according to
the bulletin of the Ministry of Agriculture no. 2/2010 – HACCP, head
1-4 and good manufacturing practices and hygiene in compliance
with the regulation (EC) n°852/2004**



Certificate validity till: 20.10.2025

Certificate No: F20221012



21.10.2022

.....
Date of the certificate
issue



.....
Head of Certification Body
CERT QUALITY SYSTEM s.r.o.



CERTIFICATE

Certification Body for certification of management systems
accredited by ČIA according to ČSN EN ISO/IEC 17021-1:2016

CERT QUALITY SYSTEM s.r.o.

confirms that the Company

K2pharm s.r.o.

Ratibořská 1651/177a, Kateřinky

CZ – 747 05 Opava

for fields of activities:

**Research, development and manufacturing
of food supplements.**

**Research, development and manufacturing
of cosmetics.**

has established and applies an Quality Management Systems
in accordance with the standard

ČSN EN ISO 9001:2016



Certificate validity till: 20.10.2025

Certificate No: Q20221013



21.10.2022

.....
Date of the certificate
issue



.....
Head of Certification Body
CERT QUALITY SYSTEM s.r.o.



Czech

CERTIFICATE

Certification Body

TÜV SÜD Czech s.r.o.

being an accredited certification body for IFS certification and having signed an agreement with the IFS owner, confirms that the processing activities of



K2pharm s.r.o.

**Ratibořská 1651/177a, 747 05 Opava, Czech Republic
COID 65706**

for the audit scope:

Production of food supplements (homogenization, sieving, granulation, pelletizing, drying, tableting, coating, capsule filling, banding) packed into plastic and aluminum packaging (doses, blisters) or in bulk.

Product scope(s): 10 - Dry products, other ingredients and supplements

Technology scope(s): C, D, E, F

meet the requirements set out in the

IFS Food

Version 6.1, November 2017

and other associated normative documents

at Foundation level



Audit date: 2019-04-09 - 2019-04-10

Register number of certificate: 12.257.719

Next audit to be performed within the time period:

Date of issue of certificate: 2019-06-04

2020-02-14 - 2020-04-24
or unannounced

Certificate valid until: 2020-06-04



Milan Kroutil
Head of certification body
Prague, 2019-06-04





CERTIFICATE

Certificate no. 12879

ERTE KOZMETİK SANAYİ VE TİCARET A.Ş.
Beysan San. Sit. Dereboyu Cad. No:4
TR- Beylikdüzü İSTANBUL

QS Zürich AG certifies that the Management System of the above mentioned company has been evaluated and meets the requirements established by the following rules:

GMP - ISO 22716: 2007

The management system includes:

**Production, Sales and Marketing of Perfumes and
Fragrances Alcoholic Products , Body Care Products, Bath
Care Products, Skin Care Products, Hair Care Products**

Certificates will be renewed every year along 3 years. The certificates which exceed the expiration date are not valid. During the period of validity of this certificate, the management system of the company must always comply with the requirements of the certified standards.

For updated amendments within the scope of certification of the present certificate, please refer to
<http://www.quality-service.ch/>



Audit date: 10.11.2016
Date of issue: 02.12.2019
Expiration date: 09.11.2020
Subject to successful surveillance audit

QS ZÜRICH AG
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info@quality-service.ch




Management