OZONO
HEALTH & BEAUTY

ISOLA D'ELBA - FIRENZE - PARMA

DERMOCOSMESI ALL'OZONO
COSMECEUTICA

PLANT MASTER FILE

1 - Name and address of the site: **IGIENE SERVICE SRL.** Limited Liability Company
Largo Pianosa, n.3
57037 PORTOFERRAIO (LI) - ITALY

2 - Factory's foundation date: **03.01.2012**

01.04.2019 - Merger with incorporation of the other owned company named Toscana Dream Srl. and creator of the registered brand **OZONO Health & Beauty**

3- Telephone/fax number/Web page/mail box :

TEL: +39 0565.915954
FAX: +39 0565.918400
Website : www.ozono-hb.it
Email: info@zono-hb.it

4 - Production group: FINISH PRODUCTS COSMETIC

5 - Type of products manufactured: SKIN CARE COSMETICS

6 - Brand name of the product: **OZONO Health & Beauty**

7 - If the factory is the main producer or operates under any license?

Yes, the factory is the main producer.

8 - If the company produce private label products?

Yes, the company produce private label products.

9 - Personnel:

- Personnel qualifications, experience and responsibilities of key quality personnel. There are two chemicals in laboratory. Plant Managers with over 20 years of experience plan and control all activities of the establishment.

- Traning program: there is an equip of adequate personnel with long time experience to perform supervise and control all plant activities. Procedures are written and known.

ABBREVIATION	JOB FUNCTION	EMPLOYEE
PDG	President	ROSSO FRANCA
MD	Managing Director	ROSSO FRANCA
DT	Technical Director (Regulatory)	GUARNERI MARIANNA
AMM	Administation	MARZOLLA ROSSELLA
PRE	Mixing	ROSSO FRANCA
R&D	Research & Development	ROSSO FRANCA
ACQ	Purchasing	CALISTRI VIOLA
CS	Customer Service	TAVERNA GAETANO
MRKT	Marketing	BERSELLI FEDERICA
F&P	Filling and Packaging	CALISTRI VIOLA
QA	Quality Assurance	ROSSO FRANCA
CQ	Quality Control	CALISTRI VIOLA
PLA	Planing	ROSSO FRANCA
RSPP	Prevention and protection Services	ROSSO FRANCA
PRD	Production	ROSSO FRANCA
MAG	Warehouse	FERRINI LAMBERTO

10 - Building and facilities:

- Administration: an office with 2 secretaries.
- Description of manufacturing areas: departments are divided according to function with adequate space and orderly arrangement.
- Material storage and warehousing: material is clearly identified and stored at proper conditions.
- Laboratories: a laboratory for R&D and CQ.
- IGIENE SERVICE guarantees that its infrastructures are in compliance with all Norm and Laws concerning safety , employees health and environmental protection.
- IGIENE SERVICE particularly has to respect Italian and European standards concerning manufacturing of Cosmetics.

11 - Equipments:

- Production: The main bulk production equipment are balances, mixer, sieves, mills, fusers, turbo-emulsifiers. Filling areas are equipped with special filling machines. The finished product is made on special packaging lines. All equipment are made in AISI 316 and are designed for easy cleaning.
- Quality control Laboratories: QC laboratory is equipped with suitable measuring instruments to guarantee conformity of raw materials and finish product.
- R&D – there is a laboratories with specific expertise. All staff has longtime knowledge in cosmetic field.
- Maintenance: All equipment are subject to a planned preventive maintenance programme according to the manufacturer's instructions.
- Qualification, validation, calibration: laboratory instruments and manufacture equipments are subject to calibration and are regularly maintained. Special procedures are established and records are kept in QC Laboratory.
- Cleaning and sanitation: At the end of any production, operators clean and sanitize the equipments according to written procedures.

12 - Documentation and certificates :

- Preparation revision and distribution of documents: the competent department prepares the quality system documents. Documents are updated when needed. Any revision is prepared, reviewed and approved by the same functions that were responsible for the first issue. The duration of archiving Original documents and record is defined according to legislation and regulations, but it's never less than three years.
- Copies of all approvals and certificate: Instructions for use and maintenance of equipment and measuring instruments, Suppliers Documents such as Certificate of Analysis for raw materials, Packaging Data Sheets, Customer documents such as Approval for Finish Product.

- The list of country that these products have been exported to them: Europe, Middles East, Colombia, Mexico, Brazil.

- Submitting the name and the country of the raw materials of the factory:
  Country origin: ITALY, EUROPE, AMERICA, JAPAN, CHINA
  Suppliers list: ACEF, HUWELL, CRODA, SABO, UNIVAR, AGIEFFE, TELLERINI SPA.

13 - Production:

- Description of the production operation: All production operations are carried out according to the Specifications agreed with the customer. Batch Records contain formulas and methods of production, including, if necessary, some details like temperature, speed, mixing time. To ensure traceability and the use of raw materials according to FIFO (Firs In First Out), every production batch is identified by a lot number.

- Handling of starting materials, packaging materials, finished products, quarantine, release and storage. Before starting any operations we check that all raw materials or packaging components are available, working areas are free to avoid mixing or cross-link contaminations. Finished products are controlled according to meet acceptance criteria and are stored with identifying code in defined area and appropriate conditions with a space for quarantined products.

- Handling of rejected materials: Quality Control carries out an investigation of rejected materials and products and decides to reject materials to suppliers or to destroy or to reprocess bulk and finished products in order to obtain the defined quality.

- In process sampling procedure and controls: Quality Control controls the specific of each batch of bulk with the standard approved by the customer. Final product sampling and controls : operators control the weight of the finished product and filling and packaging Specifications. Quality Control sends a sample to an external laboratory for microbiological analysis and releases a Certificate of Analysis.

- Reprocessing: if the decision is taken to reprocess the product, the method of reprocessing is defined and control are performed on the reprocessed product in order to verify the conformity with the acceptance criteria.

- Description of general policy for process validation: to verify the repeatability of a laboratory's formula is performed a first production (test pilot) under the supervision of R&D .Controls are carried out on batch to confirm the organoleptic (color, application) and physico-chemical parameters. Procedures for production's method, equipment, personnel are also validated. If necessary corrections are made to prototype in collaboration with production manager.

- Packaging : technical documentation contain list of materials and instruction for filling, closing, labelling and coding. Before starting, operators check that all filling and packaging materials are available, working areas, equipment and lines are free and clean.
- Labeling: Regulatory affairs department is responsible to update ingredients name according to International nomenclature, to check mistake and to verify functional declaration.

14 - Quality control:

- Description of the quality control system: Necessary tests are carried out on finished products with a release of CoA. Raw materials are check according to supplier documentation. An external microbiological laboratory ensures the absence of bacterial contamination from finished product.

- The list of instruments available in the quality control laboratory and control during processing laboratory: density, viscosity and pH meter.

15 - Distribution, complaints and product recall:

- Distribution procedure: Our company does not store the finished products. After receiving the order from the customer, manufactures and ships, so they are stocked only for inspection time. For this short period of time, however, the finished products are stored in dedicated areas under appropriate conditions.

- Handling of complaints and recalls : All complaints are reviewed, investigated and followed-up on, as appropriate. Quality Assurance retains all complaints and carries out an investigation on the concerned batch to verify if the complaint is just or not Quality Control coordinates promptly and in a timely manner the recall process. Recalled products are identified and stored separately in a secure area while awaiting a decision.

16 - Contract production and analysis:

- Assessment of GMP compliance from the contractor manufacturer will be done.

17- A brief explanation of the monitoring the site by the authorities of the countries:

- The controls for the inspection of the company is carried out by competent organizations Ministerial for protection of human health and safety (such as A.S.L., the territorial sanitary agency). We have all the necessary permits to produce safe and comply with current laws of the European Community (European Regulation 1223/2009).

Portoferraio,

IGIENE SERVICE S.r.l.
CEO & Administrator
Franca Rosso