DNV·GL

DECLARATION OF COMPLIANCE

Issued to

Orkla Health AS

Peter Møllers vei 13, 0585 Oslo, Norway

The company has been evaluated according to ISO 22000:2005 by DNV GL Business Assurance and found to meet the requirements of the basic principles of

Good Manufacturing Practice (GMP)

With the scope: Production of cod liver oil and omega 3-concentrate.

Date of evaluating: 2019-04-02 Declaration valid to: 2020-04-02

Good manufacturing practices (GMP) are the practices required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of food and beverages, cosmetics, pharmaceutical products, dietary supplements, and medical devices.
All guideline follows a few basic principles:

- Manufacturing facilities must maintain a clean and hygienic manufacturing area.
- Manufacturing facilities must maintain controlled environmental conditions in order to prevent cross-contamination from adulterants and allergens that may render the product unsafe for human consumption or use.
- Manufacturing processes must be clearly defined and controlled. All critical processes are validated to ensure consistency and compliance with specifications.
- Manufacturing processes must be controlled, and any changes to the process must be evaluated. Changes that affect the quality of the drug are validated as necessary.
- Instructions and procedures must be written in clear and unambiguous language using good documentation practices.
- Operators must be trained to carry out and document procedures.
- Records must be made, manually or electronically, during manufacture that demonstrate that all the steps required by the defined procedures and instructions were in fact taken and that the quantity and quality of the food or drug was as expected. Deviations must be investigated and documented.
- Records of manufacture (including distribution) that enable the complete history of a batch to be traced must be retained in a comprehensible and accessible form.
- Any distribution of products must minimize any risk to their quality.
- A system must be in place for recalling any batch from sale or supply.
- Complaints about marketed products must be examined, the causes of quality defects must be investigated, and appropriate measures must be taken with respect to the defective products and to prevent recurrence.

Place and date:
Høvik, 2019-08-12

Magne Sjøbakk
Lead auditor

Einar Richter Jordfald
Key Customer Manager

Lack of fulfilment of conditions as set out in the ISO 22000 Certification Agreement may render this Declaration invalid.