Lyfjastofnun
Icelandic Medicines Agency

Certificate No: IS/15/18

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued following an inspection in accordance with:
Art. 111(5) of Directive 2001/83/EC

The competent authority of Iceland confirms the following:
The manufacturer: **Lýsi hf.**
Site address: **Fiskislóð 5, Reykjavík, IS-101, Iceland**

Has been inspected in accordance with the Medicinal Products Act, nr. 93/1994, as amended, and Regulation concerning the manufacture of medicinal products, No. 893/2004, as amended.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **14th of December 2018**, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC.

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection, after which time the issuing authority should be consulted.

This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified with the issuing authority.

28 December 2018

Jón Pétur Guðmundsson
Icelandic Medicines Agency

Lyfjastofnun
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CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS

1.5 Packaging

1.5.1 Primary packing

1.5.1.1 Capsules, soft shell
1.5.1.6 Liquids for internal use
1.5.1.13 Tablets

1.5.2 Secondary packing

Any restrictions or clarifying remarks related to the scope of this certificate.

1.5: Products packed at the site are fish oil capsules, liquid fish oil and tablets that are not classified as medicinal products in Iceland.

28 December 2018

Jón Pétur Guðmundsson
Icelandic Medicines Agency

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