KM Rustfri A/S

# Certificate of Compliance

## FDA / USP Pharmacopeia Class VI

With this signature, we hereby certify that the elastomer compounds; VITON, EPDM and Silicone used in the manufacture of our hygienic sealing gaskets are in compliance with the Food and Drug Association (FDA) Code of Federation Regulation for rubber and rubber like materials. This under Title 21 § 177.2600 and also meets the criteria of the Class 1 materials classification of the 3-A Sanitary Standards U.S.D.A. and standard 51 of the N.S.F. We hereby confirm that no Phthalate Esters are contained in any plasticization agent used during the manufacturing process. We certify that the PEEK material used for our HYGASEAL gaskets is complaint with and tested to the FDA regulations Title 21. C.F.R 177.2415 for food contact applications. Also the PEEK grade 450G complies with the EC directive 202/72/EC for plastics in contact with foodstuffs.

With this signature, we hereby certify that the pharmaceutical grade elastomer compounds, EPDM (2107), Silicone (4137, 4145, 4147, 4247) and VITON (3107, 3207) from which we manufacture our parts under prescribed manufacturing procedures for pharmaceutical products have been tested and certified by the Toxicon Laboratory, Woburn, Massachusetts to be on compliance with the criteria of the U.S Pharmacopeia Class VI, sec. <88> Biological Reactivity Test in Vivo. We also certify that the Pharmaceutical grade Elastomer compounds are in compliance with the Food and Drug Association (FDA) code of Federal Regulations for rubber and rubber-like materials under Title 21, § 177.2660 and also the criteria of the class 1 materials classification of the 3-A Sanitary Standards U.S.D.A. and Standard 51 of the N.S.F. DUPont Dow Corporation has certified their medical grade platinum cured Silicone compound , Q7-4780, used in our compound 4749, to be in compliance with the criteria of the U.S Pharmacopeia, Class VI, sec. <88> Biological Reactivity Test in Vivo. We hereby certify that our Teflon (PTFE) parts are made from virgin Teflon (PTFE) which has been tested by DUPont to be in compliance with the criteria of the U.S. Pharmacopeia, Class VI, sec. <88> Biological Reactivity Test in Vivo. The Teflon (PTFE) parts meet FDA Code of Federal Regulations for Teflon (PTFE) and Flourocarbon Resins under Title 21, § 177.1550 for use in contact with food. It also meets the criteria of the Class 1 material classification of the 3-A Sanitary Standard.

KM Rustfri A/S – October 2020

Peter Melgaard CEO

Hans Dennis QHSE Manager

KM Rustfri A/S

# Certificate of Compliance

## EU Regulation (EC) No. 2023/2006

With this signature, we hereby confirm that products delivered from

KM Rustfri A/S follows good manufacturing practice according to EU regulation EC No. 2023/2006

KM Rustfri A/S has a monitored Quality System, which ensure full traceability throughout the production

KM Rustfri A/S – October 2020

Peter Melgaard CEO

Hans Dennis QHSE Manager

KM Rustfri A/S

# Certificate of Compliance

## EU Regulation (EC) No. 1935/2004

## EU Regulation (EC) No. 2023/2006

With this signature, we hereby confirm that products delivered from KM Rustfri A/S is in accordance to all articled in the EU regulation (EC) No. 1935/2004 and EU regulation (EC) No. 2023/2006

The principle underlying this regulation is that any material or article intended to come into contact directly or indirectly with food must be sufficiently inert to preclude substances from being transferred to food in quantities large enough to endanger human health or to bring about an unacceptable change in the composition of the food or a deterioration in its organoleptic properties.

KM Rustfri A/S follows good manufacturing practice, and has a monitored Quality system, which ensure full traceability throughout the production

KM Rustfri A/S – October 2020

Peter Melgaard CEO

Hans Dennis QHSE Manager

KM Rustfri A/S

# Certificate of Compliance

## EU Regulation (EC) No. 1907/2006

With this signature, we hereby confirm that we as both "downstream user" and "importer" do not ship any substances in excess of the REACH one metric ton limit.

By the very nature of the products manufactured and supplied by KM Rustfri A/S the substances contained within our products are not intended to be released from the articles under normal or reasonably foreseeable conditions of use and therefore are exempt from the REACH regulations (see Orgalime Guide to REACH section 2.1). Furthermore KM Rustfri A/S seals and gaskets do not include Substances of Very High Concern (SVHCs) –Annex XV. As a result, REACH does not require registration of any substances contained within our seals and gaskets nor is notification required. KM Rustfri A/S has assessed our compliance to this legislation and is confident that we currently meet the obligations under this act.

KM Rustfri A/S – October 2020

Peter Melgaard CEO

Hans Dennis QHSE Manager

KM Rustfri A/S

# Certificate of Compliance

## EU Regulation (EC) No. 2011/65 (RoHS 2)

KM Rustfri A/S certifies that all of its products are RoHS-2 compliant without exemptions. All products conform to the requirements of the European Union's Restriction on Use of Hazardous Substances in Electrical and Electronic Equipment (RoHS) Directive No. 2011/65 /EU.

KM Rustfri A/S understands "RoHS Compliant" to mean that banned substances are not added during the manufacturing process and finished products have upper concentrations within RoHS limits.

KM Rustfri A/S will continue to comply with and support any updates to the European Union's Restriction on Use of Hazardous Substances in Electrical and Electronic Equipment (RoHS) Directive No. 2011/65/EU.

KM Rustfri A/S – October 2020

Peter Melgaard CEO

Hans Dennis QHSE Manager