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 – August 2016

KM Rustfri A/S
Gl. Hanbjergvej 2a, DK-7800 Skive
Phone +45 97534344 Fax +45 97534393

Bo Melgaard

Quality Manager