



PRODUCT CERTIFICATE

Zertifikat Nr./Certificate No.:
201043-2016-FSMS-ITA-DNV

Datum Erste Ausgabe/Initial date:
30 Mei 2016

Gültigkeit/Valid:
31 Mei 2022 – 30 Mei 2025

Es wird bescheinigt, dass das Managementsystem / This is to certify that

ElringKlinger Kunststofftechnik GmbH

Legal Site: Etzelstr. 10 - 74321 Bietigheim-Bissingen - Germany
Production Site: Badenbergrstraße, 15 - 89520 Heidenheim - Germany

Ist in Übereinstimmung mit den Anforderungen der Norm /
Complies with the applicable requirements of:

EQUIPMENT WITH FOOD CONTACT SURFACES GMP" PROTOCOL

Diese Zertifizierung gilt für den Geltungsbereich /
This certificate is valid for the following scope:

Herstellung von Dichtungen, Membranen, Rohren, Folien , Bälge, Buchsen, Bauteilen für den direkten Kontakt mit Lebensmitteln aus PTFE (Compound oder pur) und indirektem Kontakt mit Lebensmitteln, auf Basis von PTFE (Compound oder pur), PFA, PE-UHMW, PEEK. Verwendete Technologien: Compoundherstellung, Pressen, Sintern, Drehen (IAF 14)/

Production of seals, diaphragms, tubes, foils, bellows, bushings, construction parts or billets intended for direct food contact made of PTFE (compound or pure), and indirect contact with food, made by PTFE (compound or pure) , PFA , PE-UHMW, PEEK . Technologies used : compound production , pressing , sintering , turning (IAF 14)

Ort und Datum /Place and date:
Vimercate (MB), 30 Mei 2022

Für die Zertifizierungsstelle/
For the Certification Body
DNV - Business Assurance
Via Energy Park, 14,
20871 Vimercate (MB) - Italy



Claudia Baroncini
Management Representative

Appendix to Certificate

Type of material/ Art des Materials	Product/ Product	Type food contact/ Typ Lebensmittelkontakt	Certificate/ Zertifikat
PTFE	PTFE HS17022	DIRECT indirect	<p>Test report number PA/4777/15 issued on 11.03.2016 by Fraunhofer IVV (DAKKAS accreditation ISO IESC 17025 num.D-PL-11140-04-00) (migration and extraction tests according to EU 1935/2004 and FDA 21 CFR 177.15 50</p> <p><i>Standard Datasheet HS 17022 Order Norm with supplier n.B8832 09.05.2017 EK Declaration of conformity EU 10/2011 and FDA rev 01/2018 Supplier's ROW MATERIAL 3m dyneon TFM Modified Powder 1700 declaration issued on 29.01.2018 updated to EU 79/2018</i></p>
PFA	Moldflom MF 10005 (PFA)	indirect	<p>Test report number PA/5010/17 issued on 13.04.2018 by Fraunhofer IVV (migration tests according to EU 1935/2004</p> <p>Test report number 1073-06 issued on 29.08-2006 by Fabes (accreditation ISO 17025 DAKKAS num.D-PL-14122-01-00) extraction and FDA 21 CFR 177.15 50 updated by Test report number PA/5010/17 issued on 26.04.2018 by Fraunhofer IVV</p> <p><i>EK Declaration of conformity EU 10/2011 rev 04/2018 Declaration of conformity FDA 21CFR 177.1550 rev 04/2018 Supplier's of conformity of Row material 3m Dyneon Fluorplastic PFE 6405 HTZ issued on 13.03.2018 in according to UE and FDA Regulation Order Norm B8836 issued on 04.12.2017 Data sheet 04.07.2017</i></p>
Peek	Moldflon MF 40002 (PEEK)	indirect	<p>Test report number PA/5010/17 issued on 13.04.2018 by Fraunhofer IVV (migration tests according to EU 10/2011 ,EU 1935/2004 and Reg EU 213/2018</p> <p>Test report number PA/5010/17 issued on 13.04.2018 by Fraunhofer IVV to extraction and FDA 21 CFR 177.15 50</p> <p><i>EK Declaration of conformity EU 10/2011 rev 04/2018 Declaration of conformity FDA 21CFR 177.1550 rev 04/2018 Supplier's of conformity of Row material VITREX PEEK 450G issued on 30/05/2017 in according to UE and FDA Regulation Order Norm B2887 issued on 06/04/2018 Data sheet 11.05.16</i></p>
PE -UHMW	Moldflon MO10006 (PE-UHMW Food grade)	indirect	<p>Test report number PA/5010/17 issued on 13.04.2018 by Fraunhofer IVV (overall and specific migration tests according to EU 10/2011 EU 1935/2004 and Reg EU 213/2018</p> <p>Test report number PA/5010/17 issued on 13.04.2018 by Fraunhofer IVV to extraction and FDA 21 CFR 177.15 50</p> <p><i>EK Declaration of conformity EU 10/2011 rev 04/2018 Declaration of conformity FDA 21CFR 177.1550 rev 04/2018 Supplier's of conformity of Row material QUADRANT EPP TIVAR 1000 Food Grade issued on 01/03/2018 in according to UE and FDA Regulation Order Norm B8907 issued on 07/03/2018 Data sheet 20.03.2018</i></p>