

PRODUCT CERTIFICATE

Certificate No.:
201043-2016-FSMS-ITA-DNV

Initial date:
30 May 2016

Valid:
30 May 2019 - 30 May 2022

This is to certify that

ElringKlinger Kunststofftechnik GmbH

Legal Site: Etzelstr. 10 - Bietigheim-Bissingen - 74321 Baden-Würt - Germany

Complies with the applicable requirements of:

EQUIPMENT WITH FOOD CONTACT SURFACES GMP" PROTOCOL

This certificate is valid
for the following scope:

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

(EA Sector: 14)

Luogo e Data/Place and date:
Vimercate (MB), 23 July 2019

For the Certification Body



Zeno Beltrami
Management Representative

Certificate No.: 201043-2016-FSMS-ITA-DNV
Place and date: Vimercate (MB), 23 July 2019

Appendix to Certificate

Site Name	Site Address	Site Scope
ElringKlinger Kunststofftechnik GmbH Legal and Production Site	Etzelstr. 10 Bietigheim-Bissingen 74321 Baden-Würt - Germany	Reference to scope
ElringKlinger Kunststofftechnik GmbH Production Site	Heidenheim Badenbergsstraße 15 D 89520 Heidenheim - Germany	Reference to scope

Product	Type food contact	Type of material	Migration Test
PTFE HS17022	DIRECT indirect	PTFE	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 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
Moldflom MF 10005 (PFA)	indirect	PFA	EK Declaration of conformity EU 10/2011 rev 04/2018 Declaration of conformity FDA 21CFR 177.1550 rev 04/2018 Test report number PA/5010/17 issued on 13.04.2018 by Fraunhofer IVV (migration tests according to EU 1935/2004 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 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
Moldflon MF 40002 (PEEK)	indirect	Peek	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 Test report number PA/5010/17 issued on 13.04.2018 by Fraunhofer IVV to extraction and FDA 21 CFR 177.15 50 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

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Moldflon MO10006 (PE-UHMW Food grade)	indirect	PE -UHMW	Test report number PA/5010/17 issued on 13.04.2018 by Fraunhofer IVW (overall and specific migration tests according to EU 10/2011 EU 1935/2004 and Reg EU 213/2018 Test report number PA/5010/17 issued on 13.04.2018 by Fraunhofer IVW to extraction and FDA 21 CFR 177.15 50 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
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