

PRODUCT CERTIFICATE

Zertifikat Nr.:
201043-2016-FSMS-ITA-DNV

Datum Erste Ausgabe:
30 Mei 2016

Gültigkeit:
30 Mei 2019 - 30 Mei 2022

Es wird bescheinigt, dass das Managementsystem

ElringKlinger Kunststofftechnik GmbH

Verwaltungssitz: Etzelstr. 10 - Bietigheim-Bissingen - 74321 Baden-Würt - Germany

Ist in Übereinstimmung mit den Anforderungen der Norm:

EQUIPMENT WITH FOOD CONTACT SURFACES GMP" PROTOCOL

Diese Zertifizierung gilt
für den Geltungsbereich

**Fertigung von Dichtungen, Membranen,
Schläuchen, Folien, Faltenbälgen, Buchsen,
Konstruktionsteilen und Halbzeugen für den
direkten Lebensmittelkontakt aus PTFE
(Compound oder pur) und für den
indirekten Lebensmittelkontakt aus PTFE
(Compound oder pur), PFA, PE, PEEK.
Verwendete Fertigungsverfahren:
Compound-Mischung, Pressen, Sintern,
Drehen
(EA Sektor: 14)**

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

Für die Zertifizierungsstelle



Zeno Beltrami
Management Representative

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Appendix to Certificate

Site Name	Site Address	Site Scope
ElringKlinger Kunststofftechnik GmbH Legal and Production Site	Etzelstr. 10 Bietigheim-Bissingen 74321 Baden-Würt - Germany	Bezug auf den Anwendungsbereich
ElringKlinger Kunststofftechnik GmbH Production Site	Heidenheim Badenbergstraße 15 D 89520 Heidenheim - Germany	Bezug auf den Anwendungsbereich

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 (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 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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