

January 2021

## EU-Konformitätserklärung / Letter of Conformity

### Teil 1. Mechanische Risiken / Part 1. Mechanical risk

Wir erklären hiermit, dass die nachstehend beschriebenen Persönliche Schutzausrüstungen den Anforderungen der VERORDNUNG (EU) 2016/425 DES EUROPÄISCHEN PARLAMENTS UND DES RATES vom 9. März 2016 über persönliche Schutzausrüstungen entsprechen, welche in folgend genannten harmonisierten Normen spezifiziert sind.

We herewith confirm that described Personal Protective Equipment complies with the legal provisions of the Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment, which are specified in the following harmonized standards.

Bezugnehmende relevante Normen / related relevant standards

**EN 420: 2003 - A1 2009; EN388: 2016**

Produktbeschreibung/ Product description	Baumuster-Prüfbescheinigung Nr. / Type examination certificate no.
niroflex BlueCut lite	00151/1111/2018
niroflex BlueCut lite X	00151/1111/2018
niroflex BlueCut advance	00148/1111/2018
niroflex BlueCut advance X	00148/1111/2018
niroflex BlueCut pro (EN 407:2004)	00149/1111/2018
niroflex BlueCut armguard	00095/1111/2019
niroflex BlueCut comfort	00162/1111/2019
niroflex BlueCut comfort sleeve	00232/1111/2019
niroflex WhiteCut x-tend	00150/1111/2018
niroflex WhiteCut x-treme (EN 407:2004)	00152/1111/2018
niroflex BlueCut ice (EN 511:2006)	00011/1111/2019
niroflex BlueShell ice (EN 511:2006)	00192/1111/2019
niroflex BlueShell ice dots (EN 511:2006)	00156/1111/2020

Baumusterprüfungen wurden durchgeführt durch notifizierte Stelle Nr. 2369:

Type approval examinations were performed by notified body no. 2369:

VIPO a.s.  
Gen. Svobodu 1069/4  
958 01 Partizanske  
Slovakia

Bezugnehmende relevante Normen / related relevant standards  
**EN 420: 2003 - A1 2009; EN388: 2016**

Produktbeschreibung/ Product description	Baumuster-Prüfbescheinigung Nr. / Type examination certificate no.
niroflex BlueShell smooth	0075/1968/162/12/19/3624
niroflex BlueShell sandy	0075/1968/162/12/19/3650

Baumusterprüfungen wurden durchgeführt durch notifizierte Stelle Nr. 0075:/  
Type approval examinations were performed by notified body no. 0075:

C.T.C.  
4, rue Hermann Frenkel  
69367 Lyon Cedex 07  
France

### **Teil 2. Eignung für Lebensmittelkontakt / Part 2. Suitability for food contact**

Die obigen Produkte können unbedenklich bei der Zubereitung und Behandlung von Lebensmitteln verwendet werden und dürfen dabei für kurze Zeit in direktem Kontakt mit den Lebensmitteln stehen. Es besteht keine Beschränkung hinsichtlich der Umgebungstemperatur. /  
The above products can be safely used for the preparation of food and may come into contact with this food for a short period of time. There are no restrictions regarding maximum or minimum ambient temperature.

Es wird bestätigt, dass die oben genannten Produkte den folgenden Regularien entsprechen. /  
We hereby confirm that the above products comply with the following Directives.

- Verordnung (EG) / Regulation (EC) 1935/2004 inkl. Rückverfolgbarkeit (incl. traceability)
- Verordnung (EG) Nr. / Regulation (EC) no. 10/2011
- Verordnung (EU) Nr. / Regulation (EC) no. 1282/2011 vom (dated) 10. December 2011
- Verordnung (EU) Nr. / Regulation (EC) no. 1183/2012 vom (dated) 30. November 2012
- Verordnung (EU) Nr. / Regulation (EC) no. 202/2014 vom (dated) 03. March 2014
- Verordnung (EG) Nr. 2023/2006 über gute Herstellpraxis vom 22.12.2006 /  
Regulation (EU) no. 2003/2006 of the Commission of December 22<sup>nd</sup>, 2006 on good manufacturing practice for materials and articles intended to come into contact with food  
Directive 94/62/EC, last amended by Directive 2005/20/EU (total concentration of heavy metals < 100ppm)
- Deutsches Lebensmittel- und Futtermittelgesetzbuch insb. § 30;31 (LFGB) vom 28.05.2014 /  
German Food and Commodity Goods Law § 30;31 (LFGB) dated 28.05.2014

Die Konformität wurde festgestellt aufgrund von: /  
Conformity has been established on the basis of:

- Materialselektion entsprechend dem Stand der Technik /  
material selection according state of the art knowledge
- Migrationsuntersuchungen nach Art. 17 und 18 der Verordnung (EG) Nr. 10/2011 Anhang V  
(für Artikel aus Kunststoff) /  
Migration tests according to the Regulation (EC) No. 10/2011 Annex V (for products made of plastic)

Friedrich Münch GmbH + Co KG In den Waldäckern 10 75417 Mühlacker

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75417 Mühlacker / Germany  
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Fax: + 49 (0) 70 41 / 95 44 - 55  
info@friedrich-muench.de  
info@niroflex.de  
www.niroflex.de

- Lieferantenbestätigungen / Declaration of suppliers

Die alleinige Verantwortung für die Ausstellung dieser Konformitätserklärung trägt der Hersteller./  
This declaration of conformity is issued under the sole responsibility of the manufacturer:

Friedrich Münch GmbH + Co KG

In den Waldäckern 10

75417 Mühlacker

  
Thomas Duhatschek

Technischer Leiter und QMB /

Technical Director and Quality Management Representative



**Client:** Friedrich Muench GmbH + Co KG  
In den Waldaeckern 10  
75417 Muehlacker  
Germany

**Date Issued:** JUN 2013  
**Expiry Date:** JUN 2015

## TEST CERTIFICATE

**Samples submitted:** Gloves described as Niroflex BlueCut Lite

**Test conducted:** EN 1186-5:2002 (modified) Materials and articles in contact with foodstuffs – Plastics. Test method for overall migration into aqueous food simulants by cell for 4 hours at 40°C.  
Simulant A – Distilled Water  
Simulant B – 3% Acetic Acid

EN 1186-14:2002 (modified) Materials and articles in contact with foodstuffs – Plastics. Test method for 'substitute tests' for overall migration from plastics intended to come into contact with fatty foodstuffs for 4 hours at 40°C  
Simulant D - (substitute test) 95% Ethanol

### Test results

Sample	PASS/FAIL
Niroflex BlueCut Lite	PASS

SATRA Technology Centre is an ISO 17025 accredited laboratory. All interpretations are outside the scope of UKAS Accreditation and are based on SATRA experience. This report is designed to indicate the performance of the sample tested by SATRA. SATRA have not approved the on-going quality control. It is the responsibility of purchasers to satisfy themselves that other production batches perform similarly.

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Authorized Body No. 224  
Institute for Testing and Certification, Inc., Zlín, Czech Republic  
Notified Body No. 1023 for the Directive 89/686/EEC on the PPE safety requirements  
www.itczlin.cz

# EC Type-Examination Certificate

No. 13 0638 T/NB

issued in compliance with the Czech Government Order No. 21/2003 Coll., which transposes the Council Directive 89/686/EEC concerning the PPE safety, for personal protective equipment of category II

**Protective gloves niroflex  
model BlueCut lite**

Manufacturer:

**Friedrich Muench GmbH + Co KG**

In den Waldaeckern 10, 75417 Muehlacker, Germany

VAT Id. No.: DE144528292

This Certificate confirms that above referenced personal protective equipment (PPE) fulfils the essential health and safety requirements as they are stated in the technical standards:

**ČSN EN 420:2004+A1:2010 (EN 420:2003+A1:2009), ČSN EN 388:2004 (EN 388:2003)**

The PPE is produced in compliance with the manufacturer's technical file and it can be used in complete safety for its intended purpose. The detailed product descriptions, the results of the technical file examination as well as the test results including their evaluation are presented in the ITC's Final Report No. 723300958/01/2013, which is enclosed to this Certificate.

*Conditions of this certificate use and related information:*

- 1. It applies only to the above referenced model of category II PPE submitted to test.*
- 2. It does not imply that the Notified Body has performed any surveillance or control of PPE manufacturer.*
- 3. The manufacturer is obligated to assure that all PPEs of the respective model conform to the type approved by this Certificate.*
- 4. The applicant shall inform the Notified Body of all technological changes in manufacture of the approved models and as consequence of the technical advances he shall regularly keep himself informed of any standard changes as well as modifications of testing methods conducted by the Notified Body, which shall approve these changes in necessary cases by the amendment of this Certificate.*
- 5. After fulfilling the relevant EU legislation requirements, the manufacturer shall affix to each PPE, of the above referenced model, the CE-marking according to this example:*



Issued in Zlín, 17<sup>th</sup> July 2013  
Valid until: 16<sup>th</sup> July 2018



RNDr. Radomír Čevelík  
Representative of the Notified Body No. 1023