

EU DECLARATION OF CONFORMITY (EN)

1. PPE: **Protective gloves Category III, chemical risks. Medical devices class I, for single use. Food contact**

2. Name and address of the manufacturer:

Procurator AB
P.O. Box 9504
SE-200 39 Malmö, Sweden

3. This declaration of conformity is issued under the sole responsibility of the manufacturer

4. Object of the declaration, Product number:

2331032 Worksafe Indigo Fine, powder free, blue

5. The object of the declaration described above is in conformity with the relevant Union harmonisation legislation:

**Regulation (EU) 2016/425 on Personal Protective Equipment
Council Directive 93/42/EEC concerning Medical Devices
Regulation (EU) No 1935/2004 on Materials and Articles Intended to come into Contact with Food
Regulation (EC) No 2023/2006 on Good Manufacturing Practice for Materials and Articles Intended to come into Contact with Food**

6. References to the relevant harmonised standards used or references to the other technical specifications in relation to which conformity is declared:

**EN 420:2003+A1:2009
EN 16523-1:2015
EN ISO 374-1:2016 (type C, KT),
ISO 374-4:2013, ISO 374-5:2016 (bacteria, funghi & viruses)
EN 455-1:2000, EN 455-2:2015, EN 455-3:2015, EN 455-4:2009**

7. The notified body:

Satra Technology Europe Ltd.
Notified Body No. **2777**
Bracetown Business Park, Clonee,
Dublin D15YN2P, Republic of Ireland

performed the EU type-examination (Module B) and issued the EU type-examination certificate

2777/10892-02/E01-01

Date: **8/10 2018**

Expiry Date: **18/7 2023**

8. The PPE is subject to the conformity assessment procedure (Module C2 / Module D) under surveillance of the notified body:

Satra Technology Europe Ltd.
Notified Body No. **2777**
Bracetown Business Park, Clonee,
Dublin D15YN2P, Republic of Ireland

9. The product is tested by:

ISEGA GMBH.
P.O. Box 10 05 65
63704 Aschaffenburg, Germany

Certificate registered no. **44488 U 17**

Date: **31/3 2017**

and may be safely used during the preparation and handling of foodstuff and may stand in direct contact with all types of food for a short period of time. Ratio (area/volume): $\leq 8.4\text{dm}^2 / 5\text{kg}$.

Test	Simulant used	Conditions	Result
Overall migration	A: Ethanol 10% B: Acetic acid 3% D2: Ethanol 95% D2: Isooctane	10 min at 40°C	Pass*
Overall migration	A: Ethanol 10% B: Acetic acid 3% D2: Ethanol 95% D2: Isooctane D2: Olive oil	2 hrs at 40°C	Pass*
Specific migration: Primary aromatic amines	B: Acetic acid 3%	2 hrs at 40°C	Pass*
Specific migration: N-Nitrosamines	B: Acetic acid 3%	2 hrs at 40°C	Pass*
Specific migration: Isothiazolinones	B: Acetic acid 3%	2 hrs at 40°C	Pass*
Specific migration: p-cresol-dicyclopentadiene-isobutylene, copolymer	D2: Ethanol 95% D2: Ethanol 95% D2: Isooctane D2: Isooctane	10 min at 40°C 2 hrs at 40°C 10 min at 40°C 2 hrs at 40°C	Pass*
Specific migration: Zinc	B: Acetic acid 3%	10 min at 40°C 2 hrs at 40°C	Pass*
GC-born degradation product of Didodecyl-3,3'-thiodipropionate Degradation product of dithiocarbamates Sum of alkanes	D2: Ethanol 95%	GC-MS-Screening	Pass*
GC-born degradation product of Didodecyl-3,3'-thiodipropionate Sum of alkanes	D2: Isooctane	GC-MS-Screening	Pass*
Determination of the Release of Formaldehyde	Water	30 min	Pass*
Determination of the Colour Fastness	A: Ethanol 10% B: Acetic acid 3% D2: Olive oil		Pass*
Determination of Volatile Organic Compounds		Headspace-GC/MS-Screening	Pass*
Determination of Butadiene			Pass*
Not tested for: N/A			

*Contact Procurator AB for further information

Food simulant assignment for demonstrating compliance with the overall migration limit

<i>Foods covered</i>	<i>Food simulants in which testing shall be performed</i>
all types of food	1. distilled water or water of equivalent quality or food simulant A; 2. food simulant B; and 3. food simulant D2.
all types of food except for acidic foods	1. distilled water or water of equivalent quality or food simulant A; and 2. food simulant D2.
all aqueous and alcoholic foods and milk products	food simulant D1
all aqueous, acidic and alcoholic foods and milk products	1. food simulant D1; and 2. food simulant B.
all aqueous foods and alcoholic foods up to an alcohol content of 20%	food simulant C
all aqueous and acidic foods and alcoholic foods up to an alcohol content of 20%	1. food simulant C; and 2. food simulant B.

10. Signed for and on behalf of Procurator AB

Malmö, 18/4 2019:



Anders Larsson, Category & Sourcing Director