

TECHNICKÝ LIST VÝROBKU

LATEXOVÉ RUKAVICE

Výrobca:

Akzenta International SA
Via Giuseppe Motta, 24
CH-6830, Chiasso, Švajčiarsko
T: +

Názov výrobku:

Latexové rukavice

POPIS VÝROBKU

NORMY

BALENIE

APLIKÁCIA

EXPIRÁCIA

SKLADOVANIE

NÁVOD NA POUŽITIE

LIKVIDÁCIA

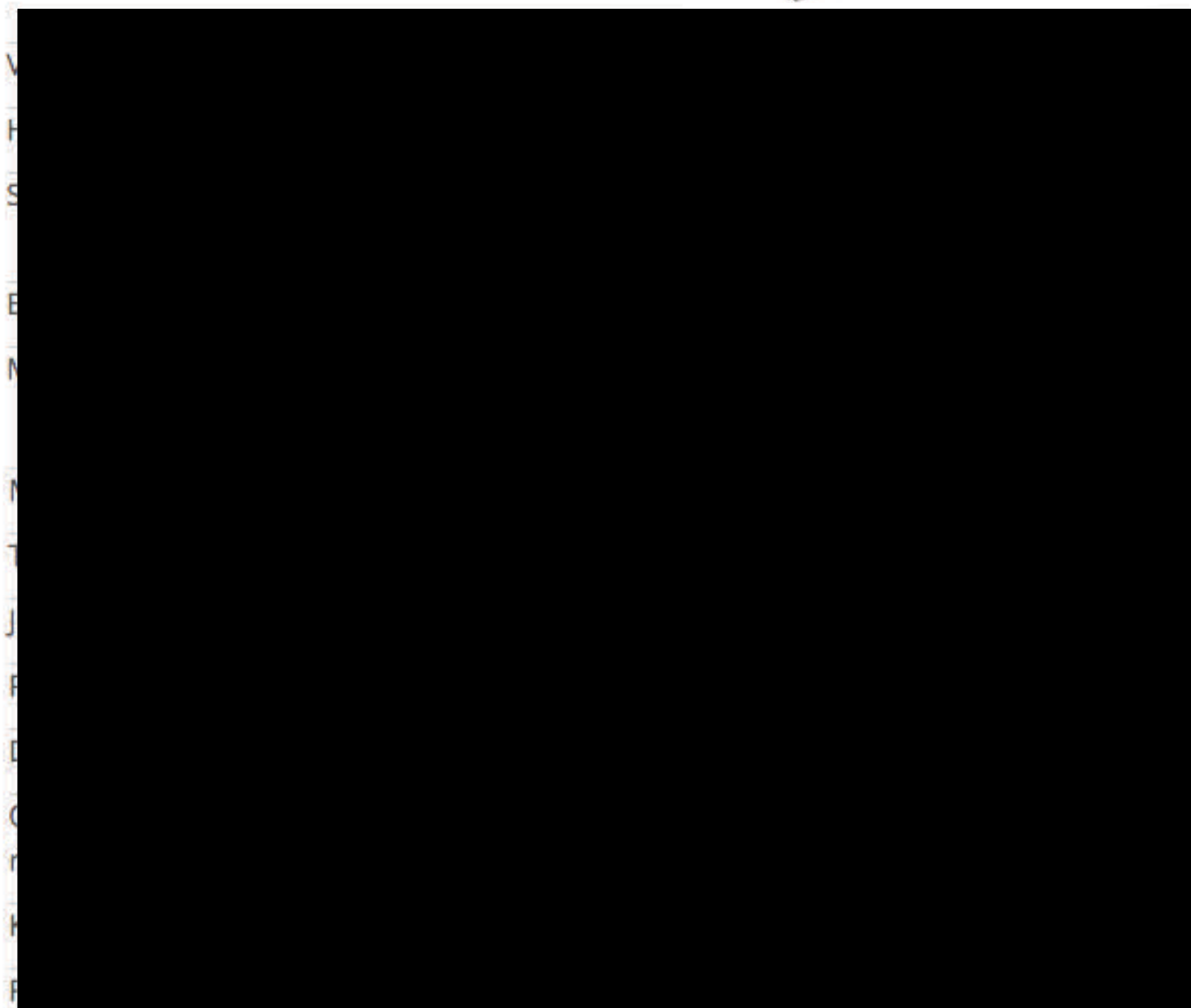
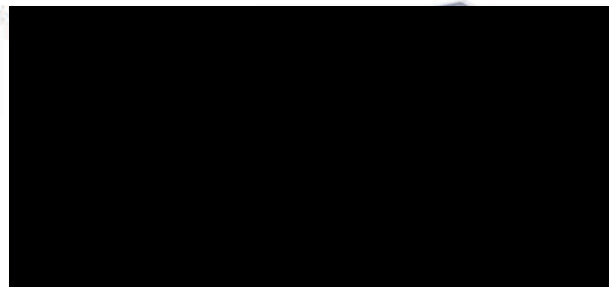
Dodávateľ:
STATUS S, s.r.o.,
Lipová 10927/21,036 08 Martin, SR

CERTIFICATES



TECHNICKÝ LIST VÝROBKU

LATEXOVÉ RUKAVICE



Dodávateľ:
STATUS S, s.r.o.,
Lipová 10927/21,036 08 Martin, SR

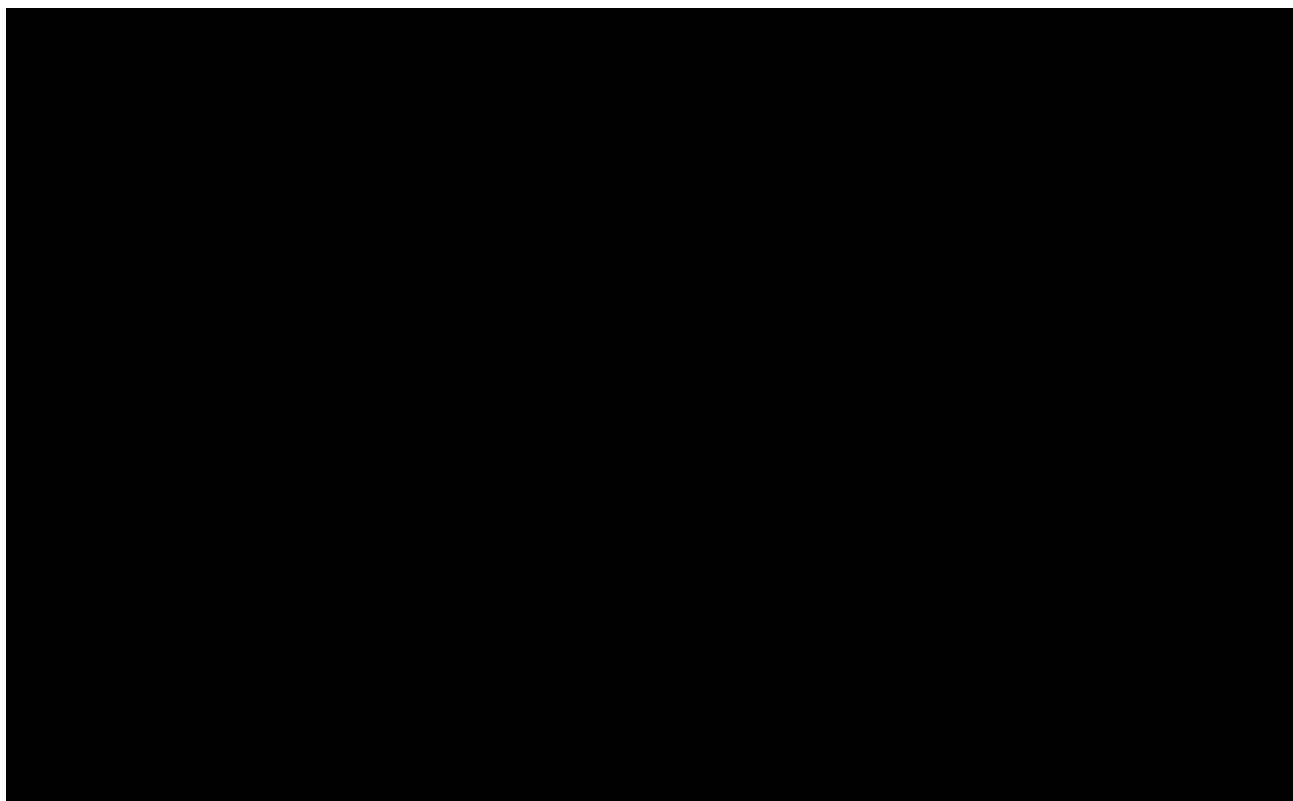
CERTIFICATES



CE

EN
455

EC-DECLARATION OF CONFORMITY



Akzenta International SA

Chiasso, 01.01.2018

Signature and stamp:

Printed name:
Position:

Luciana Piacquadio
Head of office



WWW.AKZENTA.COM
BUSINESS@AKZENTA.COM

UST. ID NR. DE815221533



VISIT US AT
WWW.AKZENTA.COM

VAT NO. CHE-337.693.284 IVA

AKZENTA INTERNATIONAL SA
VIA GIUSEPPE MOTTA 24 | CH-6830 CHIASSO

GENERAL MANAGER:
DR. JOACHIM MISSFELDT

COMPANY NO CHE-337.693.284



ASAP INTERNATIONAL SDN BHD ([REDACTED])

NO. 1, JALAN SITAR 33/6, SEKSYEN 33,
40400 SHAH ALAM, SELANGOR, MALAYSIA.

WEBSITE : www.whyasap.com

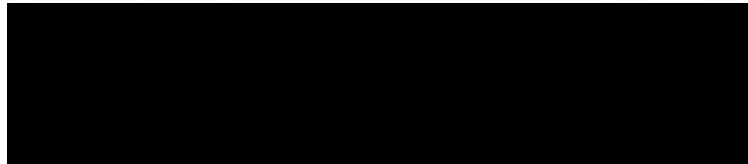
EU DECLARATION OF CONFORMITY

We,

ASAP International Sdn. Bhd.

Address: No.1, Jalan Sitar 33/6, Seksyen 33, 40400 Shah Alam,
Selangor, Malaysia

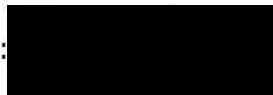
hereby declare that the PPE described hereafter:



is in conformity with the PPE Regulation (EU) 2016/425 and with the European standards EN 420:2003+A1:2009.

The above-mentioned PPE also demonstrate fulfilment to essential health and safety requirements set out in Annex II of PPE Regulation (EU) 2016/425.

Signature :



Name : Nur Dalila Umar
Position : Regulatory Affairs (RA) Associate
Date : 11th March 2019

Signed and on behalf of: ASAP International Sdn. Bhd.



NEXTECH

CERTIFICATE OF COMPLIANCE

BRIGHTWAY HOLDINGS SDN. BHD.

*Cuffing & Walleling
Washers & Drayers
Staging Area/ Pouching
Gowning Room
Lab*

Test Condition :

As per requirement of ISO 14644 the designated area listed have met the respective acceptance criteria. Testing was performed as outlined in the above standard and the results are attested to it in the

Report No:

**Date of Certification : 05/10/2018
Due Date : 05/10/2019**

**Alvin Tan Chee Kian
CPT Certified Professional**

NEXTECH SDN. BHD.

**19, Jalan Bukit Bandung 26/4, HICOM Industrial Estate
40000 Shah Alam, Selangor Darul Ehsan, Malaysia.**

EC Certificate Production Quality Assurance System: Certificate [REDACTED]

The management system of

Brightway Holdings Sdn. Bhd.

Lot 1559, Jalan Istimewa, Bt. Belah
42100 Klang, Selangor Darul Ehsan
MALAYSIA

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

[REDACTED]
Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 19 February 2016 until 19 February 2021 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 19 December 2018

Issue 8. Certified since 07 July 2000

Certification is based on reports numbered MY/KUL MY00370

Multiple certificates have been issued for this scope

The main certificate is numbered MY00/51710.00

Authorised by

[REDACTED]
[Signature]

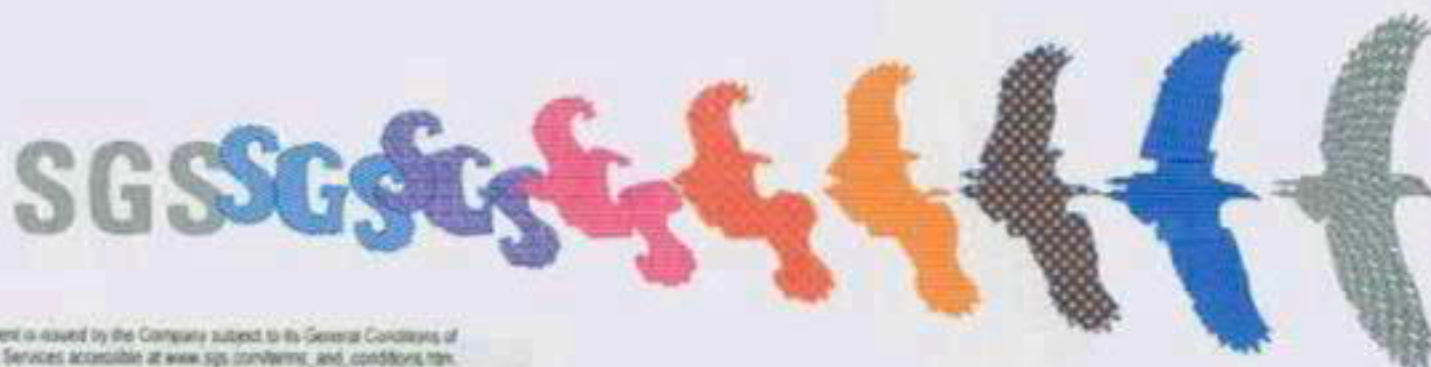
SGS United Kingdom Ltd, Notified Body 0120

2028 Worle Parkway, Weston-super-Mare, BS22 5WA UK

[REDACTED] www.sgs.com

SGS CE [REDACTED]

Page 1 of 1



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Certificate I [REDACTED]

The management system of

Brightway Holdings Sdn. Bhd. also Trading as Laglove (M) Sdn. Bhd. and Biopro (M) Sdn. Bhd.

Site 1 – Plant 1

Lot 1559, Jalan Istimewa, Bt. Belah
42100 Klang, Selangor Darul Ehsan
MALAYSIA

has been assessed and certified as meeting the requirements of

Regulation (EU) 2016/425

Module D

For the following activities

Note: All products marked CE [REDACTED] must have a valid EU type-examination certificate issued under Module B or a valid EC type-examination certificate issued under Article 10 of the PPE Directive 89/686/EEC.

This certificate is valid from 17 April 2019 until 19 February 2022 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 19 December 2021
Issue 2. Certified since 25 March 2019

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

Tom Tom

SGS FIMKO OY, Notified Body [REDACTED]

P.O. Box 30 (Särkinielementie 3), 00211 Helsinki, Finland
[REDACTED] www.sgs.com

FINAS
Finnish Accreditation Service
S003 (EN ISO/ [REDACTED])

Page 1 of 2



Certificate MY [REDACTED]

SGS

The management system of

**Brightway Holdings Sdn. Bhd.
Laglove (M) Sdn. Bhd.
Biopro (M) Sdn. Bhd.**

Lot 1559, Jalan Istimewa, Bt. Belah
42100 Klang, Selangor Darul Ehsan
MALAYSIA



has been assessed and certified as meeting the requirements of

ISO 9001:2008

For the following activities

[REDACTED]
Examination, Surgical and Industrial Gloves & Nitrile Sheath.

Further clarifications regarding the scope of this certificate and the applicability of
ISO 9001:2008 requirements may be obtained by consulting the organisation

This certificate is valid from 19 February 2016 until 14 September 2018 and
remains valid subject to satisfactory surveillance audits.

Re certification audit due before 14 August 2018

Issue 8. Certified since 07 July 2000

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by

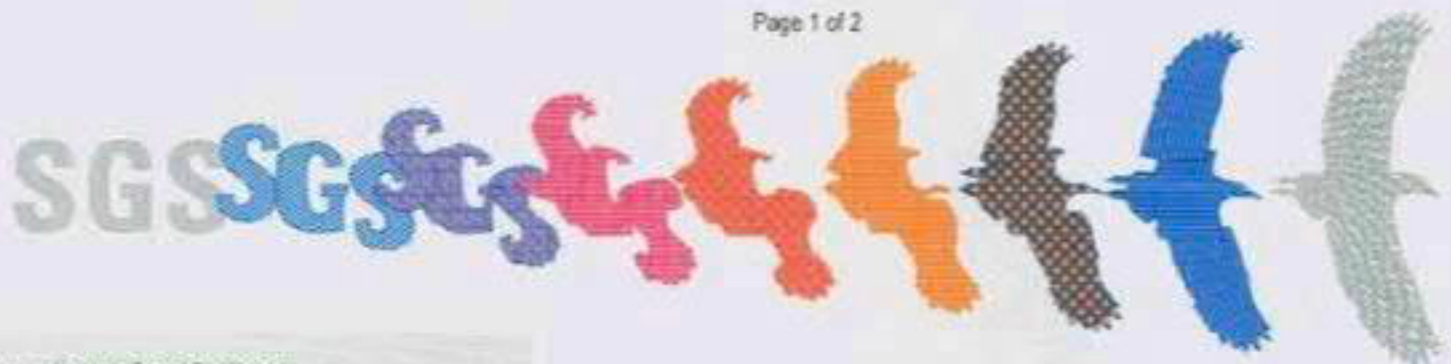
[REDACTED]



SGS United Kingdom Ltd. Systems & Services Certification
Rossmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
[REDACTED] www.sgs.com

SGS 90 [REDACTED]

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prosecuted to the fullest extent of the law.

TOP GLOVE**TOP QUALITY, TOP EFFICIENCY****TOP GLOVE SDN. BHD.****The World's Largest Manufacturer of Gloves****GOOD HEALTH, SAFETY FIRST & BE HONEST**

A member of Top Glove Corporation Bhd, a Public Listed Company on Bursa Malaysia & Singapore Exchange.

FACTORY 9 : Lot 4969, Jalan Teratai, Batu 6, Off Jalan Meru, 41050 Klang, Selangor D.E., Malaysia.

☎ [REDACTED] ✉ sales@topglove.com.my 🌐 www.topglove.com

BUSINESS DIRECTION : To Produce Consistently High Quality Gloves At Efficient Low Cost.

FACILITIES : 42 Factories (Malaysia, Thailand & China), 682 Production Lines, 64 Billion Gloves Per Annum, 18,000 Employees.

MARKET : Exports to 195 countries worldwide with Marketing Offices in the USA, Germany and Brazil.

DECLARATION OF CONFORMITY

Manufacturing Site : TOP GLOVE SDN. BHD
: Lot 4969, Jalan Teratai, Batu 6,
Off Jalan Meru, 41050 Klang,
Selangor Darul Ehsan
Malaysia

European Authorized Representative : Top Glove Europe GmbH
Bliersheimer Str. 80 A,
47229 Duisburg,
Germany.
Tel.: +49-(0)2065-76421-0,
Fax: +49-(0)2065-76421-19

Name of Device : Latex Examination Gloves
Type : [REDACTED]
Classification : Class I, Non Sterile
Conformity Assessment Procedure : Annex VII
Conformity Route : Self Declaration

We herewith declare with our own responsibility that above mentioned product(s) with CE mark is fully compliance with Essential Requirement of the EC Council Directive 93/42/EEC 14th June 1993 concerned medical devices, amended by Council Directive 2007/47/EC.

Competent Authority : Bezirksregierung Düsseldorf,
Postfach 300865, 40408 Düsseldorf.

Registration Date : 31 March 2010

Registration No : [REDACTED]

DoC Issuance date : 29th July 2020

DoC Expiry date : 29th July 2021

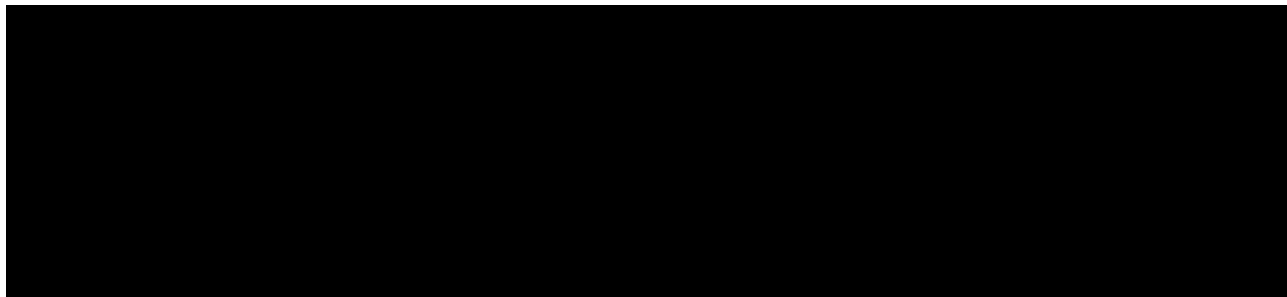
[REDACTED]
Name: Pn. Noor Akilah Saidin
Designation: Deputy General Manager, RA
[REDACTED]

**"TO PREVENT CORRUPTION & BRIBERY. CORRUPTION & BRIBERY IS A CRIME.
BE HONEST AND NO CHEATING"**

#20

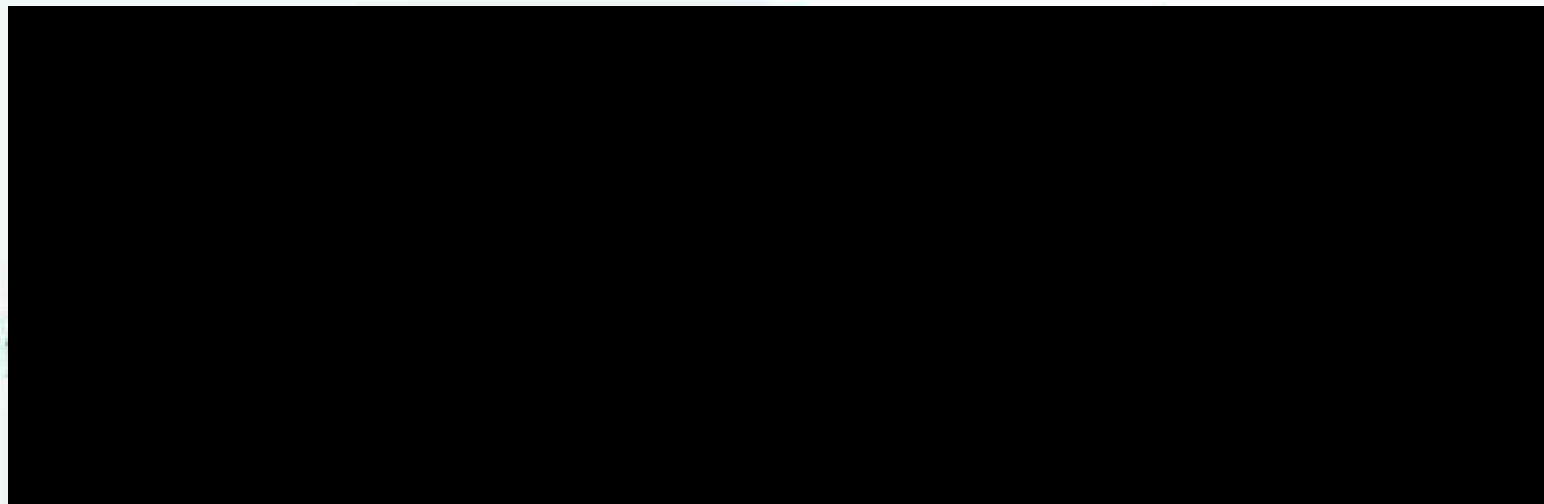
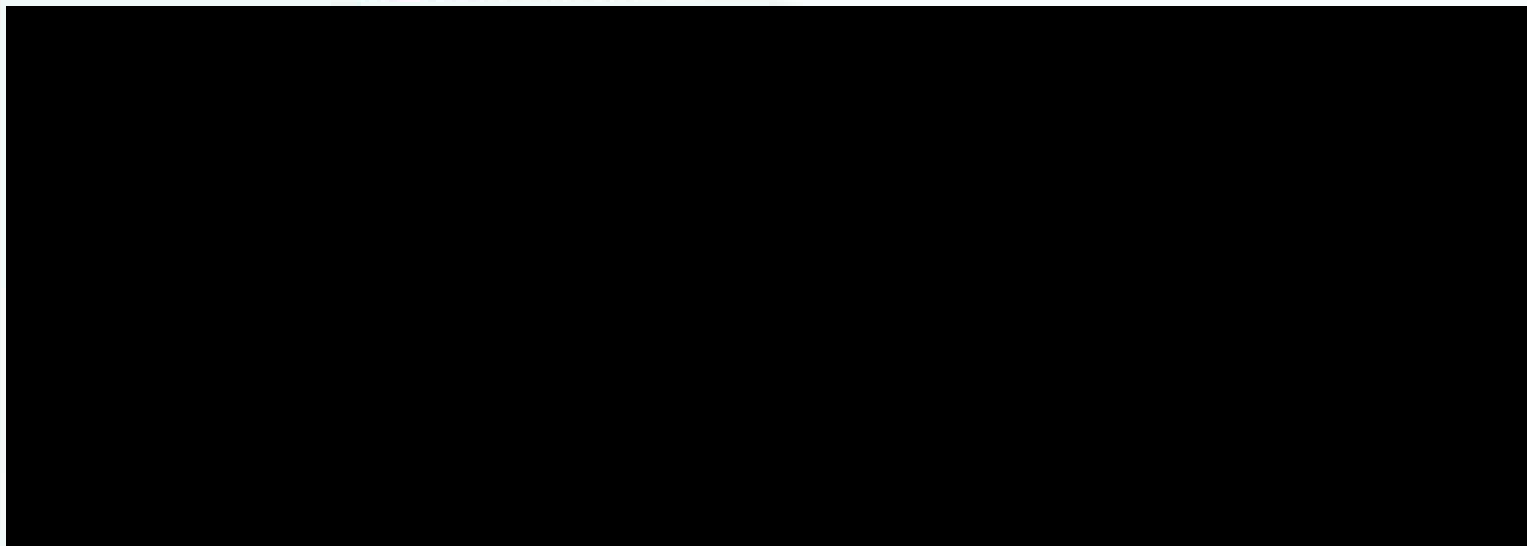
DP

Návod na použitie a údržbu jednorazových rukavíc



Návod na nasadenie rukavíc

Návod na odstránenie rukavíc



Príloha č. 2 - Návrh na plnenie kritéria na vyhodnotenie ponúk a identifikačné údaje uchádzača

Obchodné meno uchádzača: STATUS S, s.r.o.
Sídlo uchádzača: Lipová 10927/21, 036 08 Martin
IČO: 44015828
Meno a priezvisko štatutárneho zástupcu: Igor Pramuk, konateľ
IČ DPH: SK2022560287
Názov banky: Tatra Banka, a.s.
Číslo účtu (IBAN):
Telefónne číslo: +421
E-mailová adresa: pramukova.status@gmail.com

Predmet zákazky: „Ochranné jednorazové latexové rukavice“

Kritérium na vyhodnotenie ponúk: najnižšia cena za celý predmet zákazky v EUR s DPH.

Celková cena za predmet zákazky v EUR bez DPH	Výška DPH	Celková cena za predmet zákazky v EUR s DPH
20 280,00	4 056,00	24 336,00

Z toho:	Cena v EUR bez DPH	Výška DPH	Cena v EUR s DPH
Jednorazové latexové rukavice v množstve 30 000ks (veľkosť S)	3 042,00	608,40	3 650,40
Jednorazové latexové rukavice v množstve 120 000ks (veľkosť M)	12 168,00	2 433,60	14 601,60
Jednorazové latexové rukavice v množstve 50 000ks (veľkosť L)	5 070,00	1 014,00	6 084,00

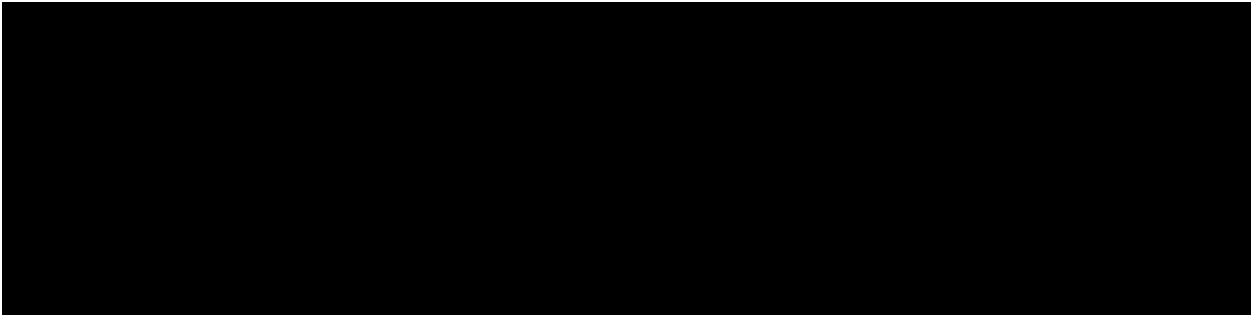
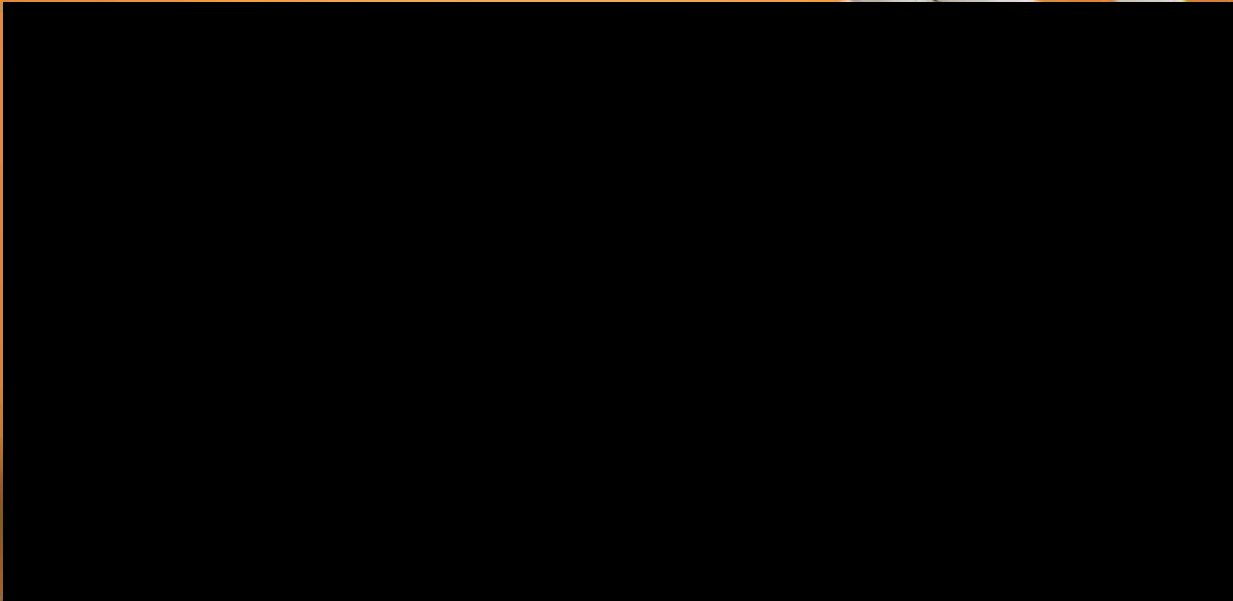
Cena uvedená uchádzačom obsahuje všetky náklady, ktoré uchádzačovi vzniknú v súvislosti s plnením predmetnej zákazky.

Som – ~~Nie som~~ platiteľom DPH (nehodiace sa preškrtnite)

Ak uchádzač nie je platiteľom DPH, na túto skutočnosť upozorní verejného obstarávateľa. Ak uchádzač nie je platcom DPH, ním uvedená cena bude považovaná za konečnú aj v prípade, ak by sa počas plnenia predmetu zákazky stal platiteľom DPH. V prípade, ak uchádzač je platiteľom DPH, avšak jeho sídlo je v inom členskom štáte EÚ alebo sídli mimo EÚ, uvedie v ponuke cenu, ktorá bude rozdelená na ním navrhovanú cenu bez DPH, výšku DPH a aj cenu s DPH podľa slovenských právnych predpisov (20%), aj keď samotnú DPH nebude fakturovať.

V Martine, dňa 29.01.2021

.....
Igor Pramuk, konateľ



VÝROBCA
ASAP

POUŽITIE



TECHNICKÝ LIST VÝROBKU

LATEXOVÉ RUKAVICE

Značka: Brightway
 Názov výrobku: [REDACTED]
 Výrobca: Brightway Holdings Snd. Bhd.
 Veľkosť: [REDACTED]
 Vyrobené v Malajzii.



POPIS VÝROBKU

NORMY

BALENIE

URČENIE

EXPIRÁCIA

SKLADOVANIE

NÁVOD NA POUŽITIE

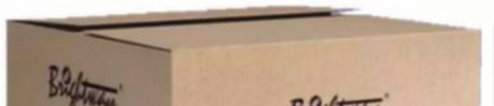
LIKVIDÁCIA

Dodávateľ:
STATUS S, s.r.o.,
Lipová 10927/21,036 08 Martin, SR



TECHNICKÝ LIST VÝROBKU

BALENIE



KARTÓN:

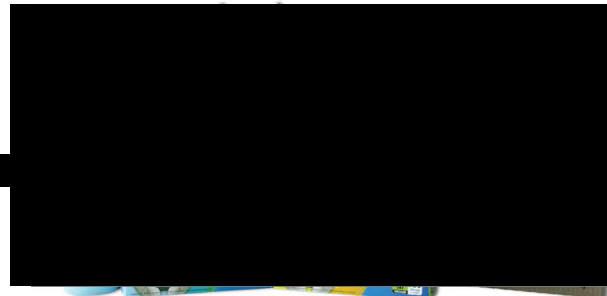
Dodávateľ:
STATUS S, s.r.o.,
Lipová 10927/21,036 08 Martin, SR

CE

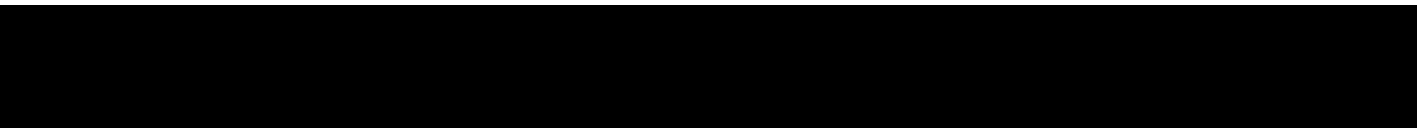
TECHNICKÝLIST VÝROBKU

LATEXOVÉ RUKAVICE

Výrobca: TOP GLOVE SND. BHD
Názov výrobku: 
EU autorizovaný zástupca: TOP GLOVE EUROPE Gm
Veľkosť: 



POPIS VÝROBKU



NORMY




BALENIE



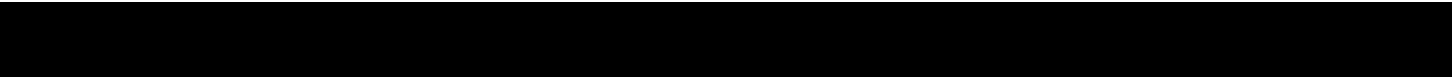
URČENIE




EXPIRÁCIA



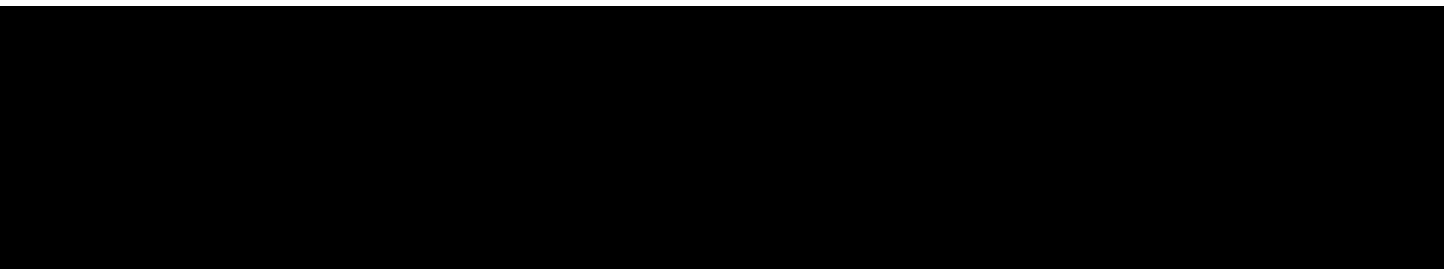

SKLADOVANIE



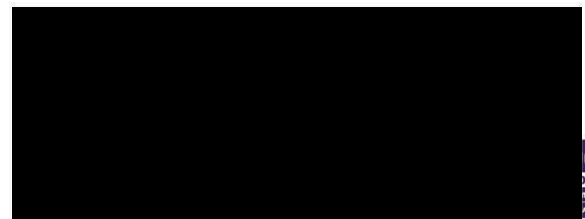
NÁVOD NA POUŽITIE



LIKVIDÁCIA



Dodávateľ:
STATUS S, s.r.o.,
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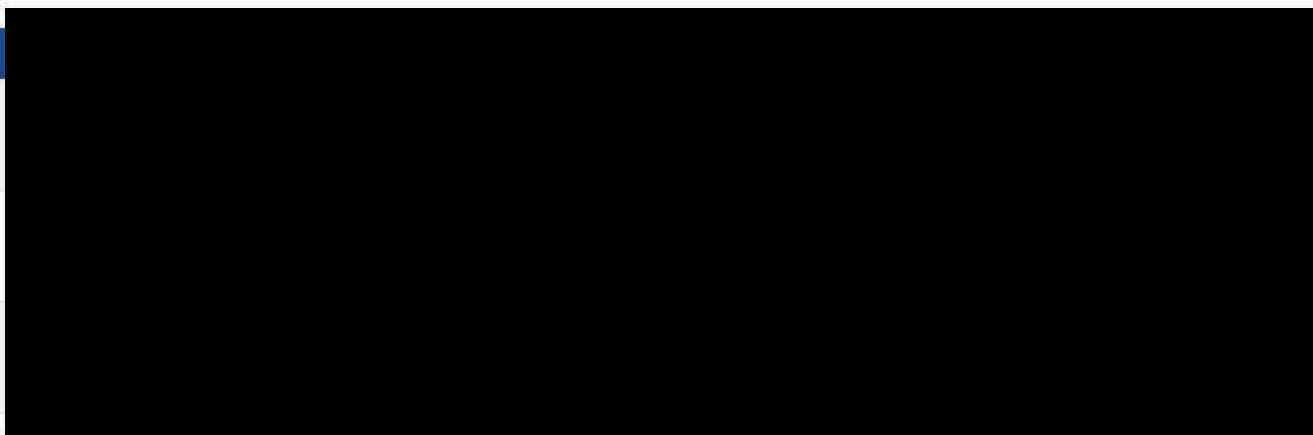
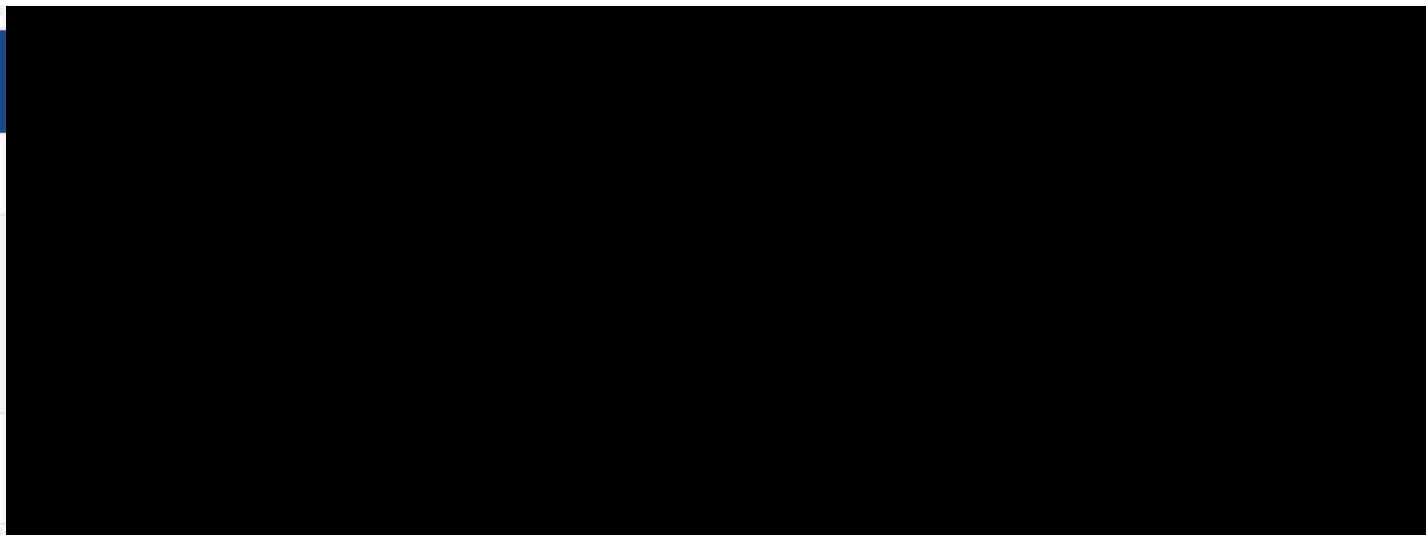
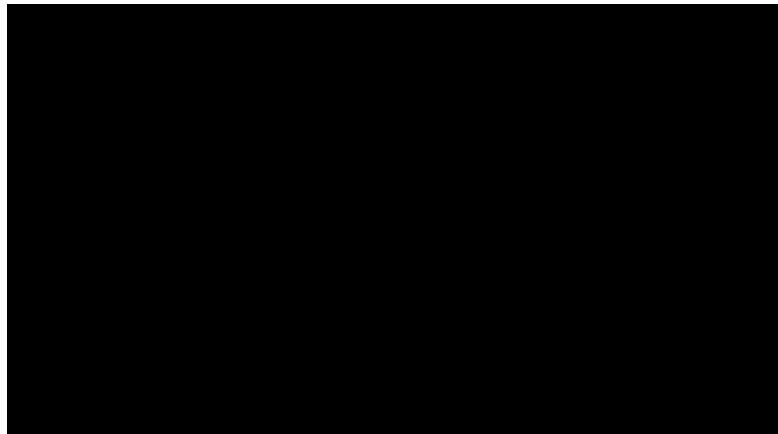
TECHNICKÝ LIST VÝROBKU

LATEXOVÉ RUKAVICE

Výrobca:
TOP GLOVE SND. BHD

Názov výrobku:

EU autorizovaný zástupca:
TOP GLOVE EUROPE GmbH



CE

Dodávateľ:
STATUS S, s.r.o.,
Lipová 10927/21, 036 08 Martin, SR

