

TECHNICKÝ LIST VÝROBKU

LATEXOVÉ RUKAVICE

Výrobca:

Akzenta International SA
Via Giuseppe Motta, 24
CH-6830, Chiasso, Švajčiarsko
T: [REDACTED]

Názov výrobku:

Veľkosť:

[REDACTED]



SKLADOVANIE

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

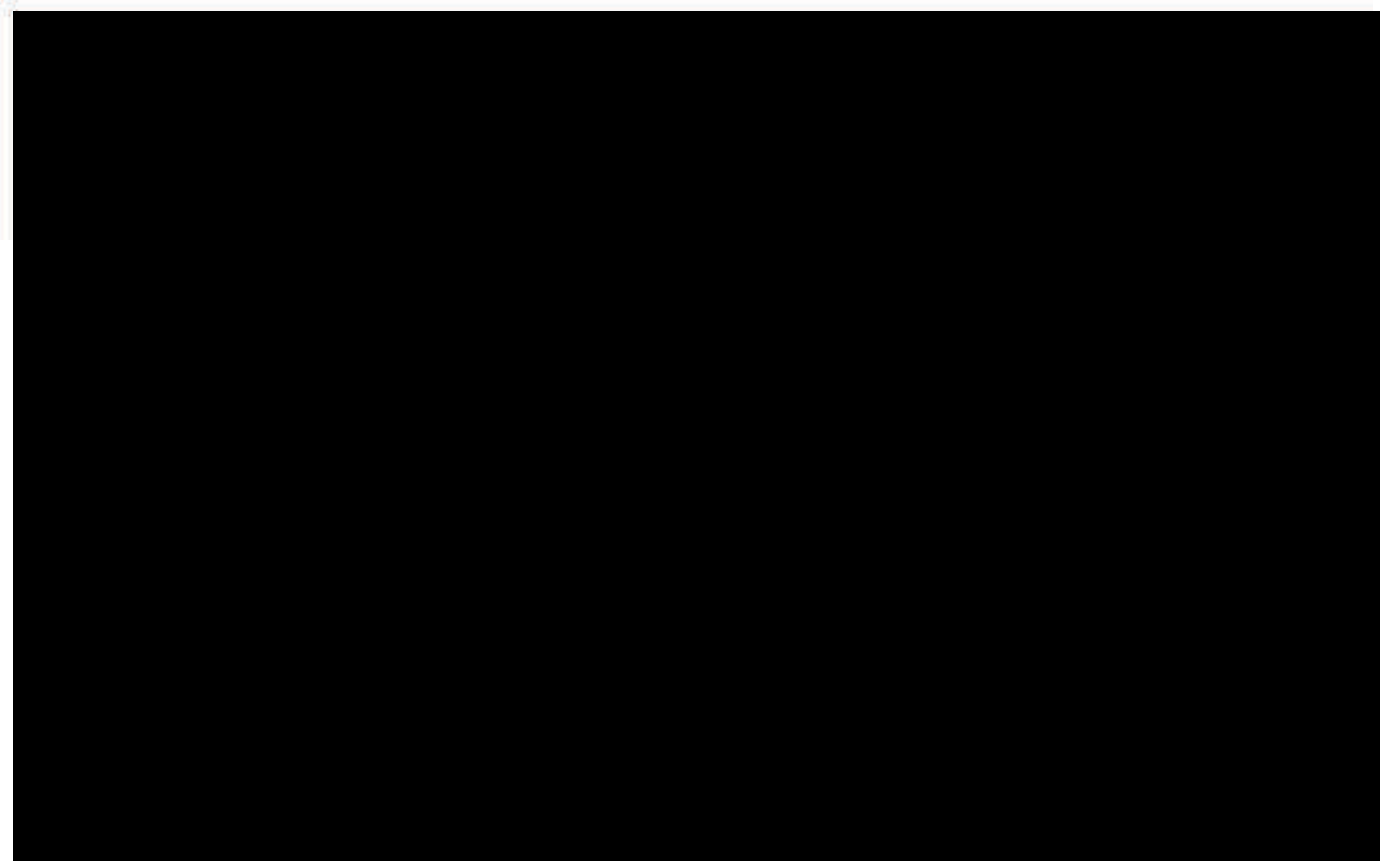
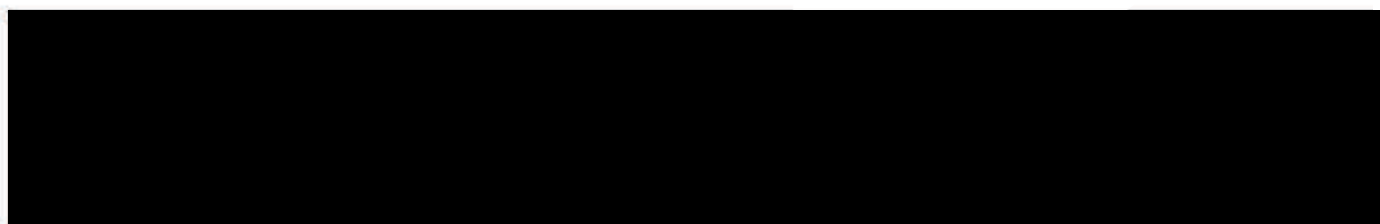
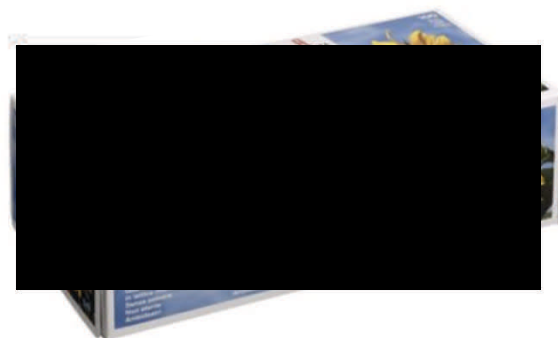
CERTIFICATES



EN
455

TECHNICKÝ LIST VÝROBKU

LATEXOVÉ RUKAVICE



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

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EC-DECLARATION OF CONFORMITY

Product:



non sterile, powder-free

Class I

We declare that the above mentioned product satisfies the requirements laid down in MDD 93/42/EEC, as amended by the Council directive 2007/47/EC.

Requirements of the EN 455 parts 1, 2, 3, 4:

- Water tightness test: gloves shall not leak when tested in accordance with clause 5. Sample size and allowable number on non-conforming gloves in accordance with ISO 2859-1, general inspection level I, AQL 1.5
- Tests were performed on gloves to ensure an acceptable performance of the products (physical and biological tests).
- The product passed all quality inspection methods in accordance with shelf life determination requirements.

The gloves are manufactured according to ISA 13485:2003 and EN ISO 13485:2012 Quality Management Systems and are certified by TUV SUD America Inc. 10 Centennial Drive Peabody, MA 01960 USA.

Akzenta International SA

Chiasso, 01.01.2018

Signature and stamp:

Printed name:

Luciana Piacquadio

Position:

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

NEXTECH

MB

CERTIFICATE OF COMPLIANCE

BRIGHTWAY HOLDINGS SDN. BHD.

<i>Cuffing & Walleling</i>	<i>(ISO Class 5)</i>
<i>Washers & Drayers</i>	<i>(ISO Class 5)</i>
<i>Staging Area/ Pouching</i>	<i>(ISO Class 5)</i>
<i>Gowning Room</i>	<i>(ISO Class 7)</i>
<i>Lab</i>	<i>(ISO Class 7)</i>

Test Condition : At Rest

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: [REDACTED]

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.

SGS

Certificate [REDACTED]

The management system of

**Brightway Holdings Sdn. Bhd.
also trading as Laglove (M) Sdn. Bhd.
and 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 13485:2016
EN ISO 13485:2016**

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 02 April 2019 until 19 February 2022
and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 19 December 2021
Issue 12. Certified since 07 July 2000

Expiry date of last certificate: 19 February 2019
End date of last recertification audit: 30 November 2018

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

Authorised by



SGS United Kingdom Ltd
Rossmore Business Park, Ellesmere Port, Cheshire, CH85 3EN, UK
[REDACTED] www.sgs.com

HC SGS 13 [REDACTED]

Page 1 of 2



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Certificate [REDACTED] issued

SGS

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

**ISO 13485:2016
EN ISO 13485:2016**



Issue 12

Detailed scope

**Manufacture of Non Sterile Natural (Latex) and Synthetic Latex (Nitrile)
Examination & Sterile Surgical Gloves.**

Additional facilities

**Laglove (M) Sdn. Bhd.
Lot 478, Jalan Simpang Balak, Off Batu 13
Jalan Cheras, 43000 Kajang, Selangor Darul Ehsan
MALAYSIA**

**Biopro (M) Sdn. Bhd.
Lot 14, PT 4204 Lingkaran Sultan Hishamuddin
North Port Industrial Estate
42000 Port Klang, Selangor Darul Ehsan
MALAYSIA**



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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

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 [REDACTED]

Multiple certificates have been issued for this scope

The main certificate is numbered [REDACTED]

Authorised by

SGS United Kingdom Ltd, Notified Body [REDACTED]

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

www.sgs.com

SGS C [REDACTED]

Page 1 of 1



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Certificate

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

Manufacture of Chemical Protective Latex and Nitrile Gloves.

Note: All products marked CE0598 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



SGS FIMKO OY, Notified Body

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

Page 1 of 2



Certificate

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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

**Manufacture of Natural (Latex) and Synthetic Latex (Nitrile)
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.

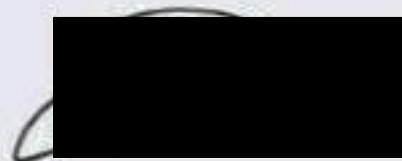
Re certification audit due before 14 August 2018

Issue 8. Certified since 07 July 2000

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by



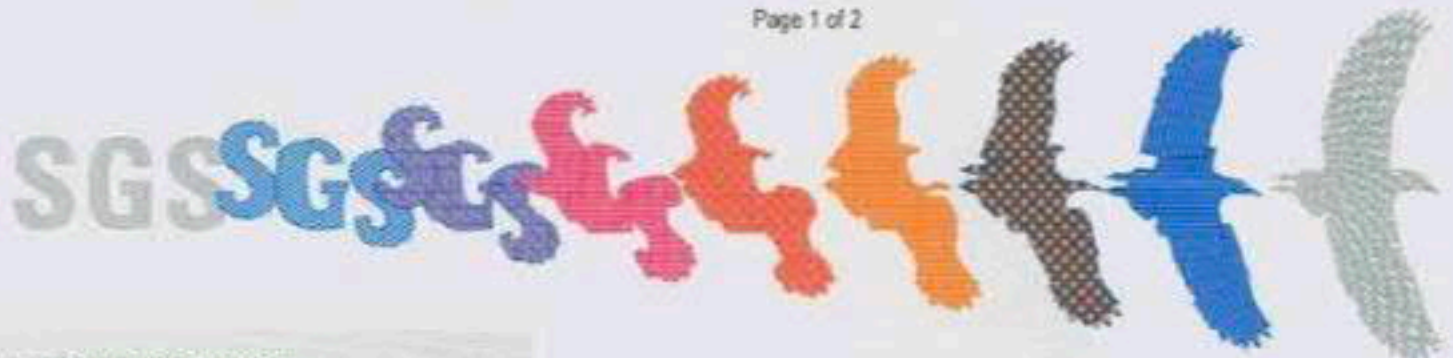
SGS United Kingdom Ltd. Systems & Services Certification
Rostmore Business Park, Ellesmere Port, Cheshire, CH65 3EN, UK
www.sgs.com



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prosecuted to the fullest extent of the law.

TECHNICKÝ LIST VÝROBKU



*If you can
DREAM IT
you can do it*

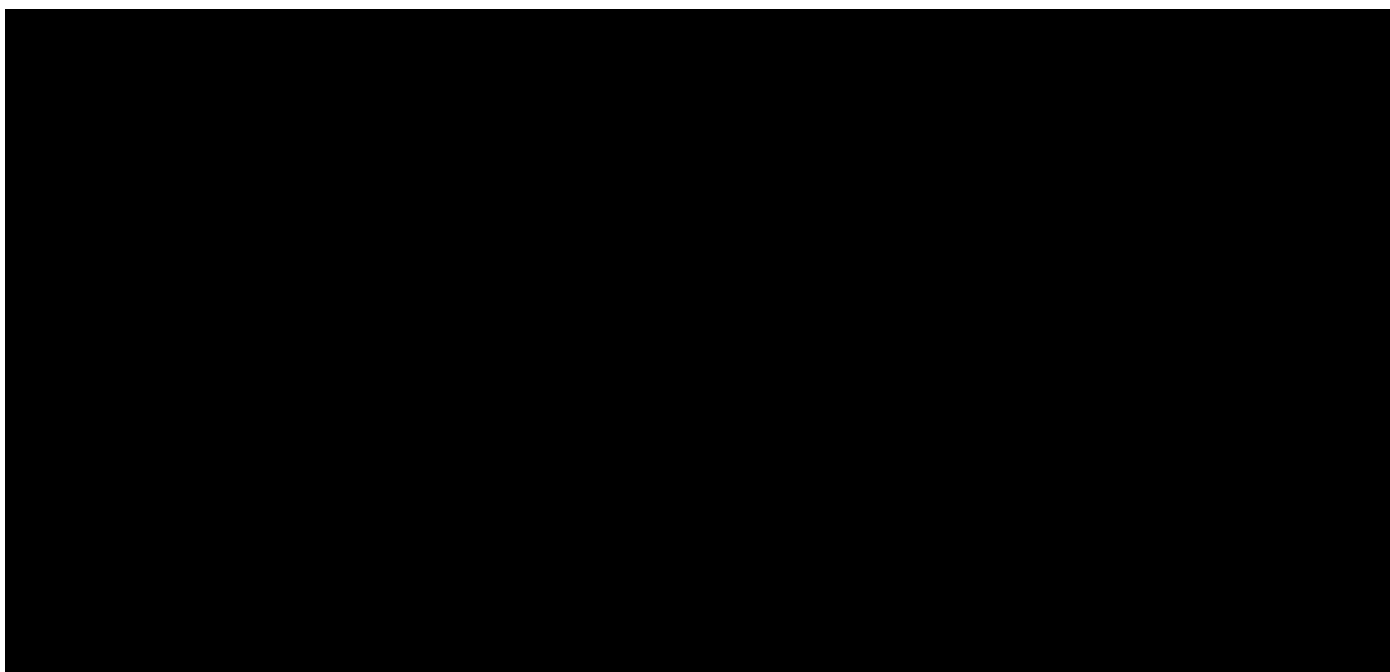
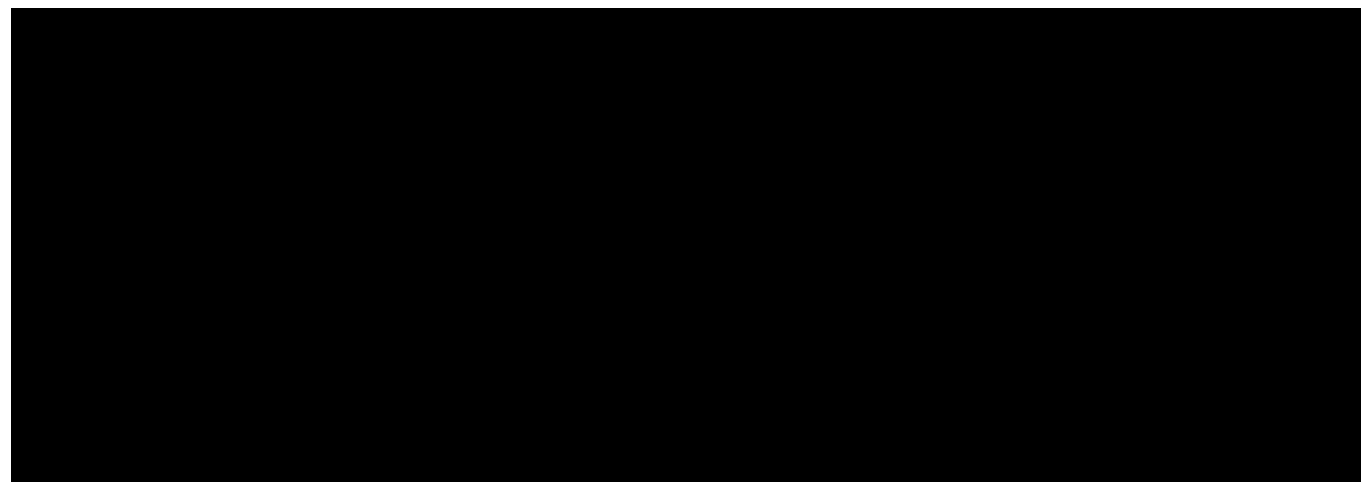
Výrobca:

MY TICARET VE MEDIKAL
Ömerli, General Şükrü Koraltı Cd.
İstanbul, Turecko

MY Medikal

Názov výrobku:

Veľkosť:



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

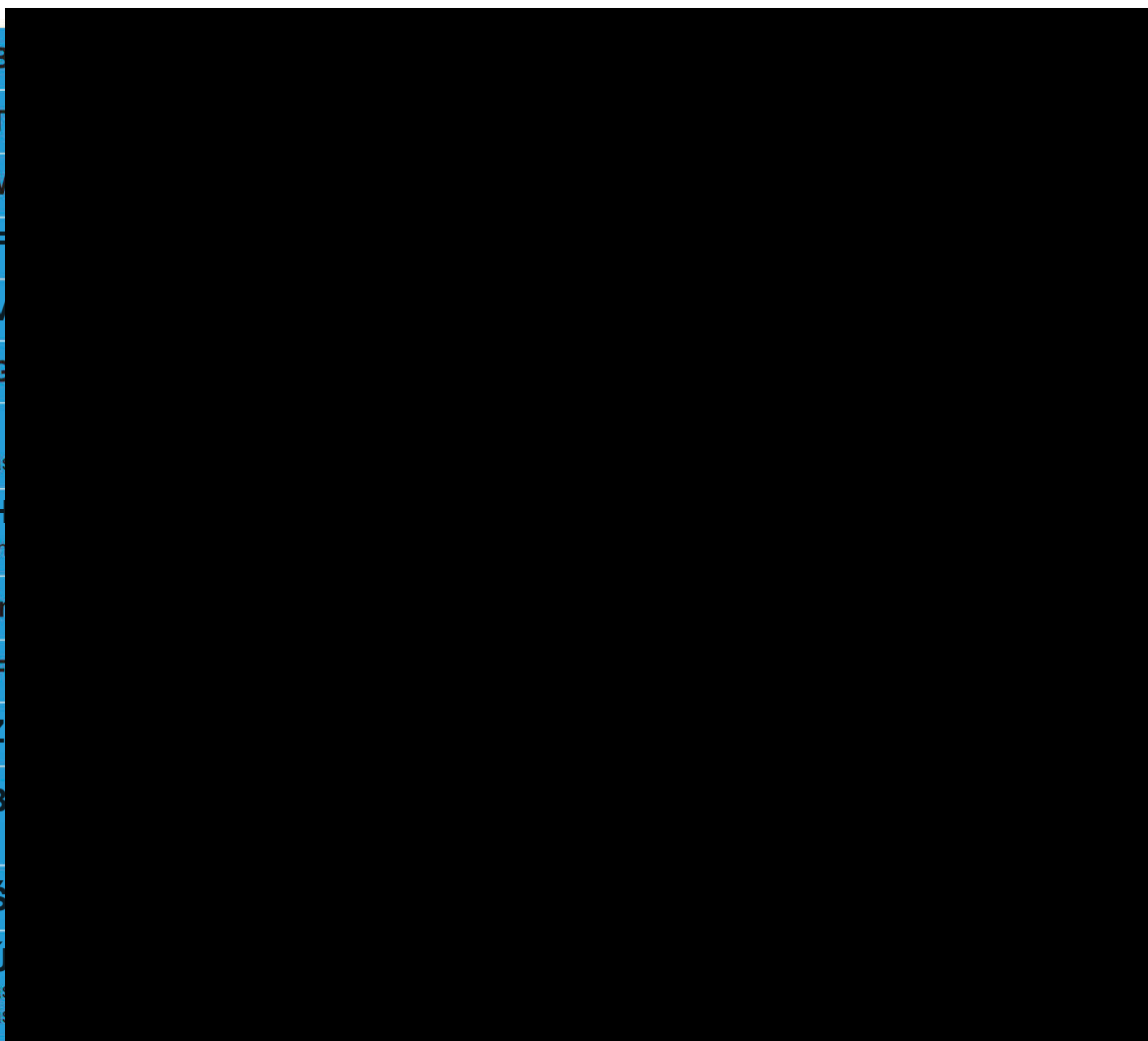
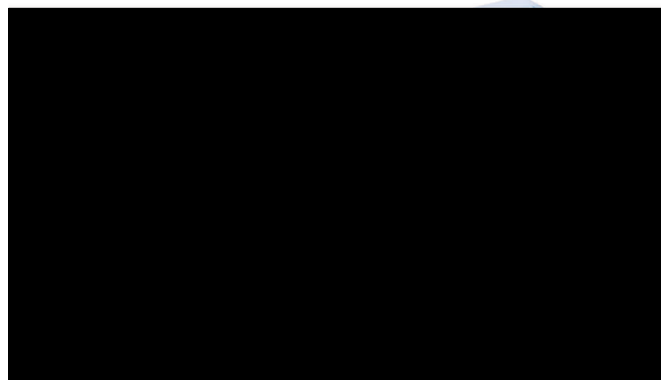
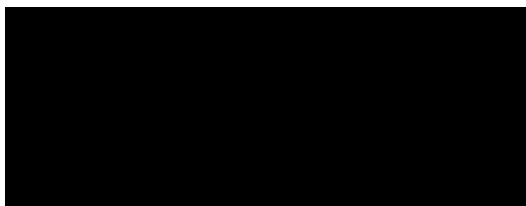
CERTIFICATES



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TECHNICKÝ LIST VÝROBKU



www.mymedikal.com.tr

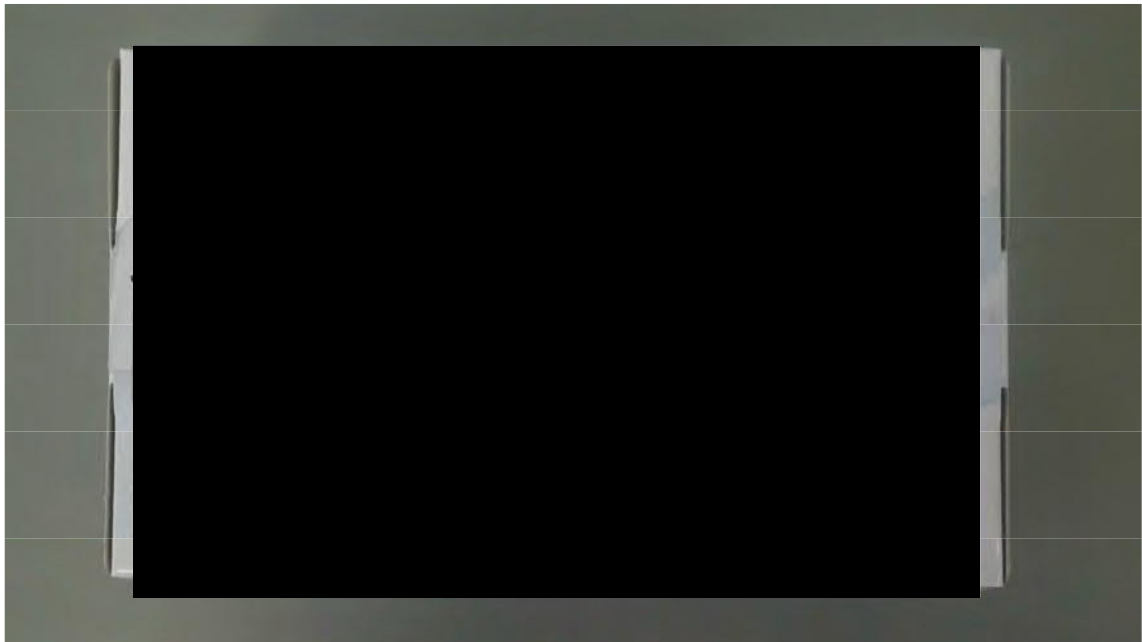
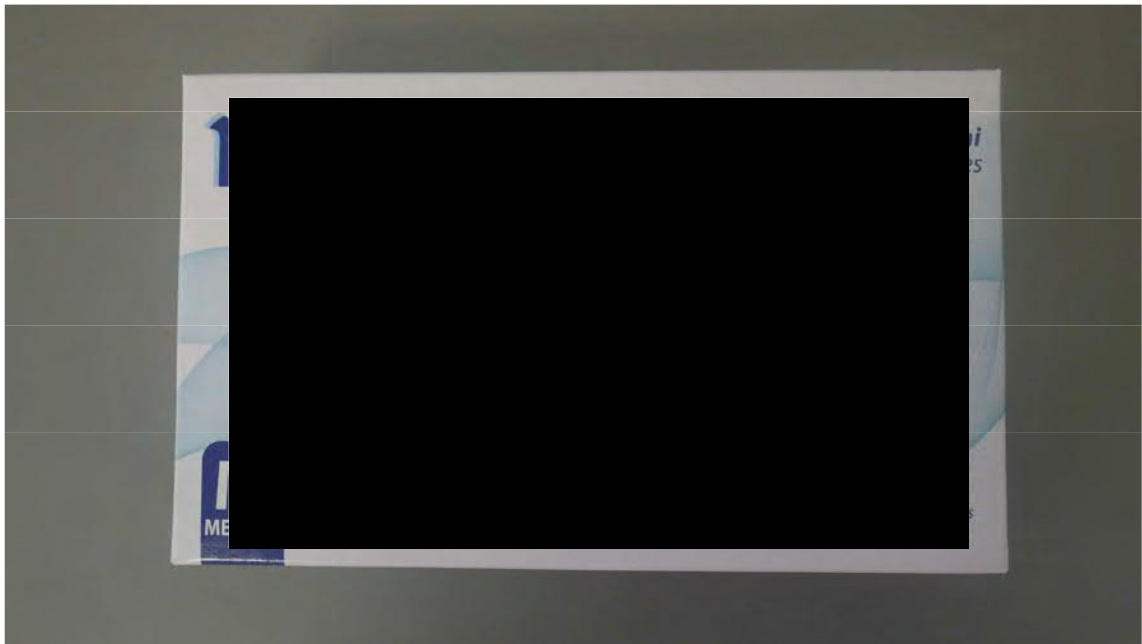
Dodávateľ:
STATUS S, s.r.o.,
Lipová 10927/21,036 08 Martin, SR

CERTIFICATES



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455

[REDACTED] VES





EC DECLARATION OF CONFORMITY

Manufacturer's Name and Address : MY TİCARET VE MEDİKAL A.Ş.
Ömerli Mah. General Şükrü Koralı Cad. No :33
Arnavutköy-İstanbul/TURKEY

Name Of Device : [REDACTED]

Type and Registration/Catalog No : Powdered Latex Examination Gloves - [REDACTED]
Powder Free Latex Examination Gloves - [REDACTED]
Powder Free Nitrile Examination Gloves - [REDACTED]

Brand : [REDACTED]

Classification : Class I

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.

Verification Certificates : Quality Management System EN ISO13485:2016
Certificate No: ISO 02 836 1179
Quality Management System EN ISO9001:2015
Certificate No: ISO 01 940 117



Standards

: EN 374-2 Protective gloves against dangerous chemicals and microorganisms-Part 2: Determination of resistance to penetration.

EN 16523-1+A1 Determination of material resistance to permeation by chemicals-Part 1: Permeation by potentially hazardous liquid chemicals under conditions of continuous contact. (EN 374-3 standard has been revised as EN 16523-1+A1)

EN 374-4 Protective gloves against dangerous chemicals and microorganisms-Part 4: Determination of resistance to degradation by chemicals.

EN 374-5 Protective gloves against dangerous chemicals and microorganisms-Part 2: Terms and performance rules for microorganism risks.

EN 455-1 Medical gloves for single use Part 1: Requirements and testing for freedom from holes.

EN 455-2 Medical gloves for single use Part 2: Requirements and testing for physical properties.

EN 455-3 Medical gloves for single use Part 3: Requirements and testing for biological evaluation.

EN 455-4 Medical gloves for single use Part 4: Requirements and testing for shelf life determination.

EN ISO 10993-1 Biological evaluation of medical devices-Part-1: Evaluation and testing within a risk management process.

Authorised Signatory

Name-Surname

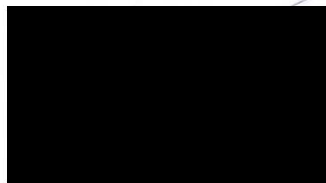
: MURAT YILDIZ

Position

: CEO

Signed

:



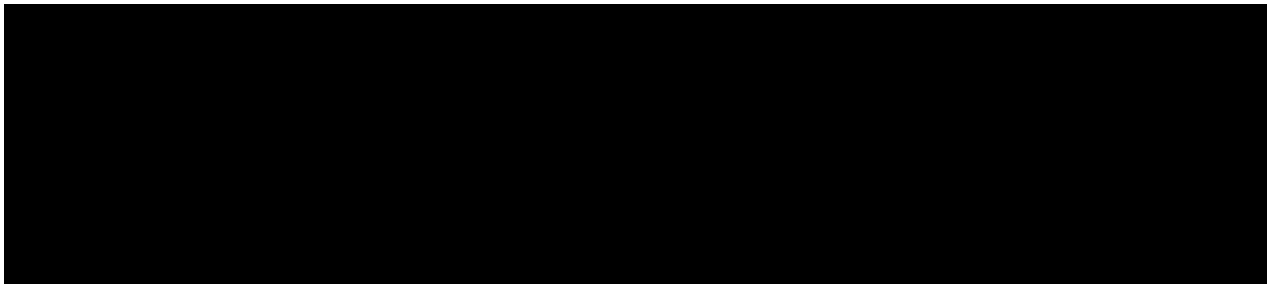
Date

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22.03.2020

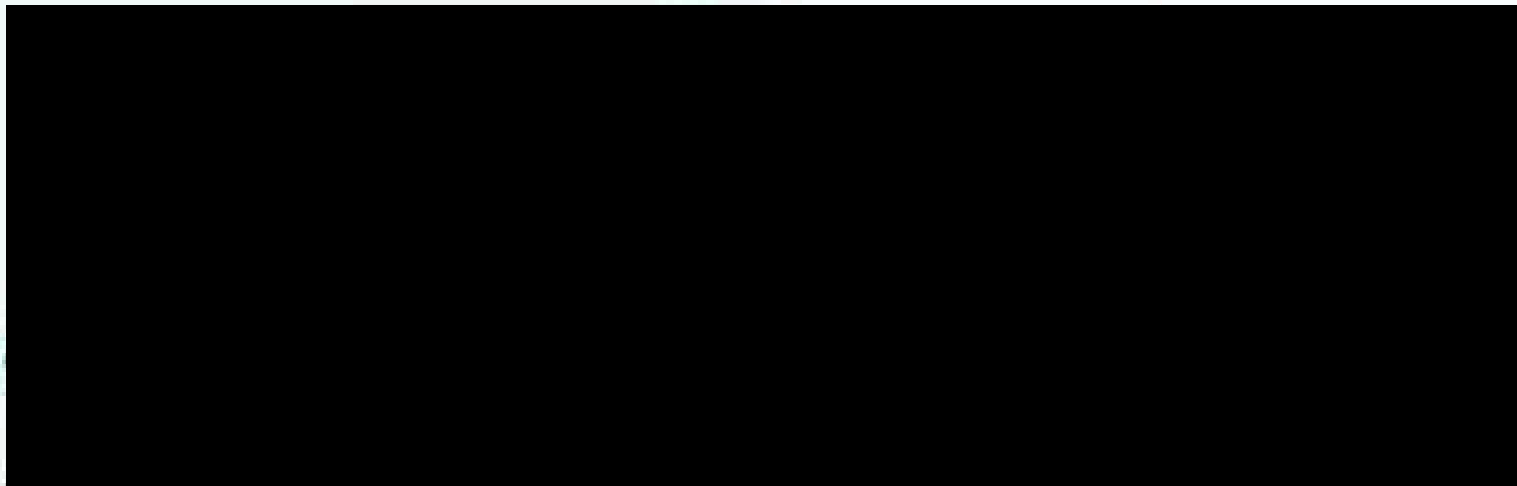
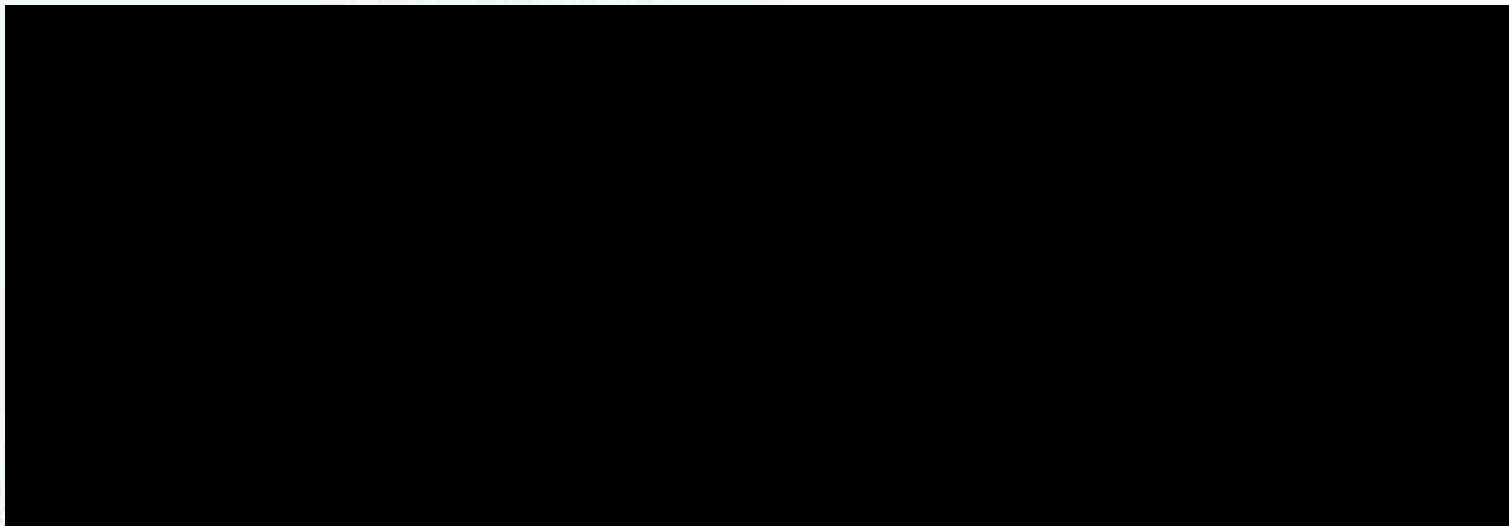


Návod na použitie a údržbu jednorazových rukavíc



Návod na nasadenie rukavíc

Návod na odstránenie rukavíc





Hlavné mesto SR Bratislava
Primaciálne nám. 1
814 99 Bratislava

Dynamický nákupný systém
Výzva č. 24
„Ochranné jednorazové latexové
rukavice“

1. 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:	FIO BANKA
Číslo účtu (IBAN):	[REDACTED]
Telefónne číslo:	09 [REDACTED]
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 20%	Celková cena za predmet zákazky v EUR s DPH
17 578,00	3 515,60	21 093,60

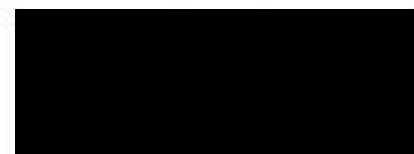
Z toho:	Cena v EUR bez DPH	Výška DPH	Cena v EUR s DPH
Jednorazové latexové rukavice v množstve 30 000ks (veľkosť S)	2 636,70	527,34	3 164,04
Jednorazové latexové rukavice v množstve 120 000ks (veľkosť M)	10 546,80	2 109,36	12 656,16
Jednorazové latexové rukavice v množstve 50 000ks (veľkosť L)	4 394,50	878,90	5 273,40

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 03.03.2021



Igor Pramuk, konateľ

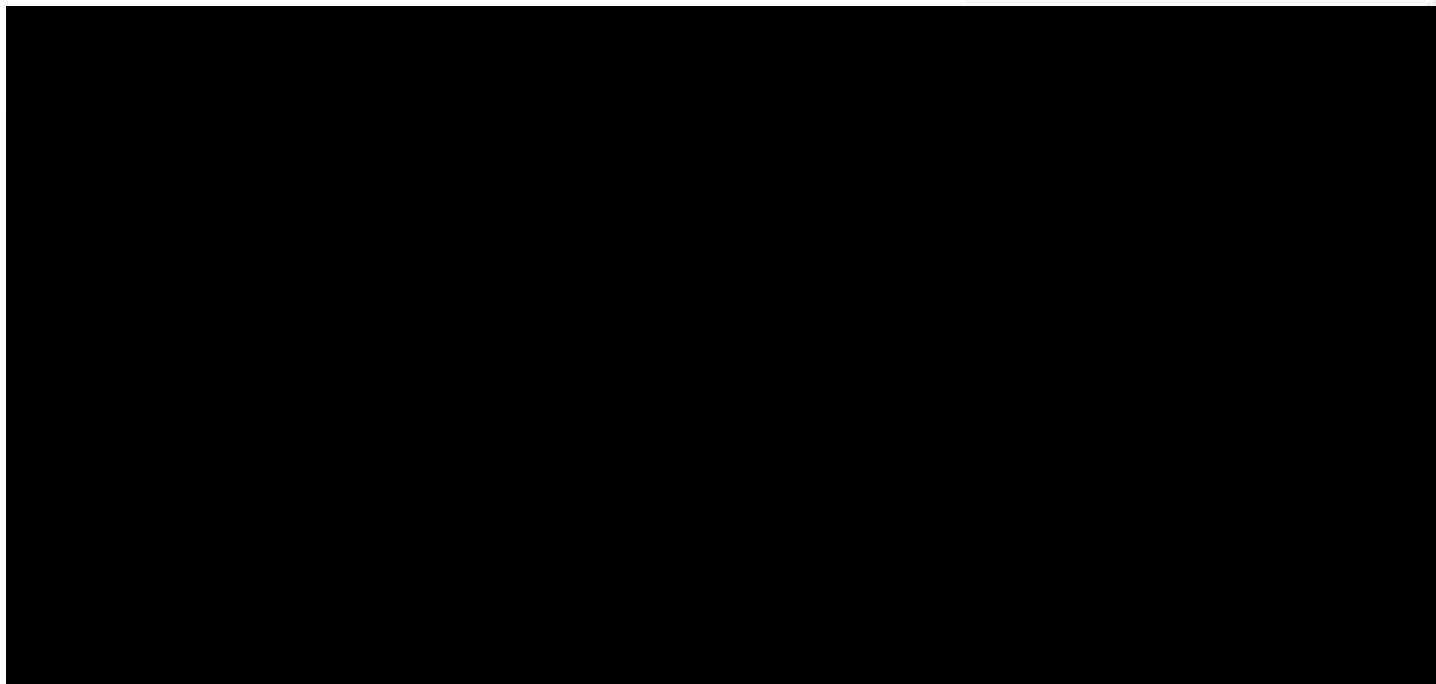
TECHNICKÝLIST VÝROBKU

Brightway®

Značka:
Názov výrobku:
Výrobca:
Veľkosť:
Vyrobené v Malajzii.

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

TECHNICKÝ LIST VÝROBKU



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

CE

