

Certificate of Designation



Client Ref. **THA/1999/09/03**

Issued To: **Phoenix Rubber Products Company Limited** **Legal Manufacturer [SRN: Not yet available]**
1/7 Bangna Thani Building,
3rd Floor, Room 3B,
Soi Bangna-Trad 34
Bangna Tai, Bangna
Bangkok 10260
Thailand

Issued By: **Advena Limited** **EC-REP [SRN: MT-AR-00000234]**
Tower Business Centre, 2nd Flr, Tower
Street, Swatar, BKR 4013. Malta.

EU Competent Authority: **Malta Medicines Authority (MMA)**
Sir Temi Zammit Buildings, Malta Life
Sciences Park, San Gwann SGN 3000
Malta.
Tel: +356 2343 9000
Email: info.medicinesauthority@gov.mt

In accordance with the Mandate executed by both the Legal Manufacturer and Advena Limited, this Certificate of Designation is issued and confirms the period of representation. Furthermore, this certificate confirms the medical devices Advena Limited acts as EU Authorised Representative for the Legal Manufacturer.

The devices listed in Appendix A must indicate Advena Ltd as the EU Authorised Representative, and in the following format, as applicable to EU legislation:

EC	REP	Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta
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Anthony Kirby – Managing Director (Malta)

Date of Issue: 11 March 2021 **AR Cover Begins:** 01 April 2021 **AR Cover Ends:** 31 March 2022

This certificate is subject to the organisation maintaining their documentation in compliance with the EU legislation as indicated in this certificate.

This certificate is for the exclusive use of Advena Ltd's clients and is provided pursuant of the European Authorised Representative agreement (Mandate) between Advena Ltd and the client. Advena's responsibility and liability is limited to the terms and conditions of this agreement. Advena Ltd assumes no liability to any party for any loss, expense or damage occasioned by the use of this certificate and the European Authorised Representative agreement (Mandate). Only the client is authorised to copy or distribute this certificate. Any use of the Advena Ltd name by others who are not covered by the above agreement, or any similar contract, is prohibited. This certificate remains valid until the expiry date has been reached or has been terminated by Advena Limited.

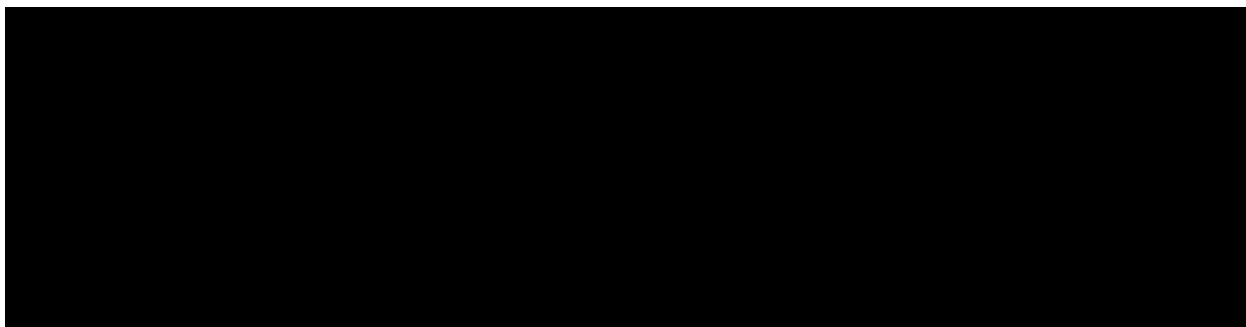
Appendix A



Product Details, Names or Trade Names	EU Legislation	Classification	Date of Declaration
Examination Gloves	MDD	Class I	22/10/2020

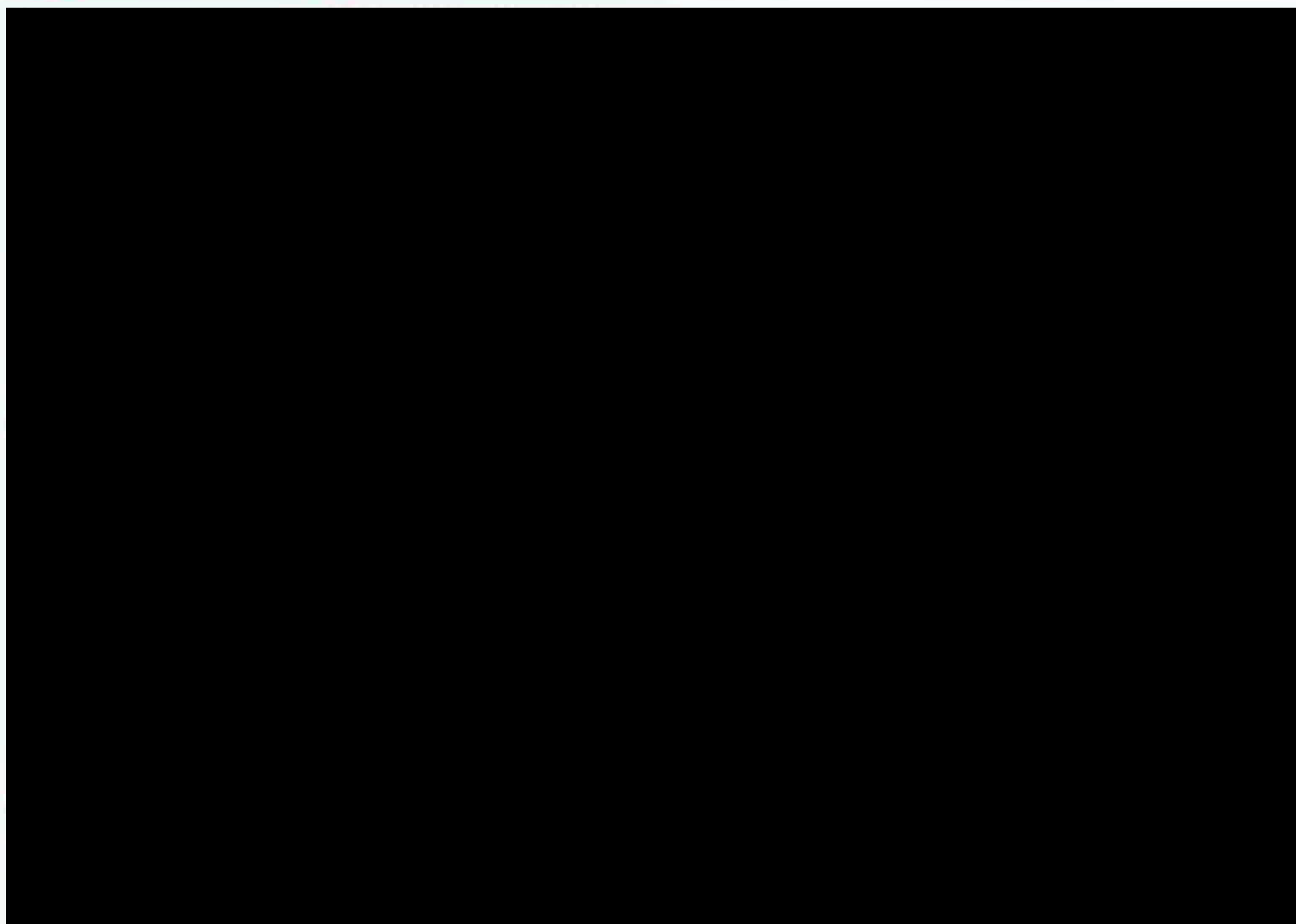


Návod na použitie a údržbu jednorazových rukavíc



Návod na nasadenie rukavíc

Návod na odstránenie rukavíc



y
e

EC Declaration of Conformity

Manufacturer's Name : "Redacted for public use"
Manufacturer's Address : "Redacted for public use"
Conformity Route : **Self Declaration**
Product Commercial Brand : **OnePlus**

We here declare that we are exclusively responsible for the above-mentioned product(s) with CE Mark is full compliance with Essential Requirement of the EC Council Directive 93/42/EEC 14th June 1993 concerning medical devices, amended by Council Directive 2007/ 47/ EC. Also, it complies with PPE Regulation (EU) 2016/425 as a Category III.

Description Of The Product: Latex Examination Glove

Product Type : **POWDERED AND POWDER FREE**

UMDNS Code : **11882**

Conformity Assessment Procedure : **ANNEX VII**

Applicable EC Directives : **MEDICAL DEVICES DIRECTIVE 93/42/EEC**

Applicable Harmonised Standards : **TS EN 455-1, TS EN 455-2, TS EN 455-3, TS EN 455-4
TS EN 374-2, TS EN 374-3, TS EN 374-4, TS EN 374-5
ISO 9001, EN 420:2003 + A1:2009, EN ISO 374-1, EN 16253-1:2015
EN ISO 374-5:2016, EN 374-4:2013**

Applicable National Technical Standards and Specifications

Classifications : **CLASS-I / NON STERILE**

Certificate Number : **19121002**

Certificate Code : "Redacted for public use"

Certificate Issue Date : **28.10.2020**

Certificate Validity Date : **28.10.2021**

Company Official

(Authorized Signature and Title)

Procurement Manger

DR. MAJED ALHARIRI

"Redacted for public use"

declares that the Medical Devices Directive 93/42/EEC has fulfilled the applicable requirements and responsibility has been taken for the above-described product groups. The product groups described above have been controlled depending on internal production controls.



Príloha č. 2 - Návrh na plnenie kritérií

Identifikačné údaje:

Názov zákazky: „Výzva č. 3 – Jednorazové latexové rukavice“

Uchádzač: STATUS S, s.r.o.

Adresa sídla: Lipová 10927/21, 036 08 Martin, SR

IČO: 440158828

Číslo účtu (IBAN): 

Telefónne číslo: 

E-mailová adresa: @gmail.com

Ponuková cena v súlade s opisom predmetu zákazky:

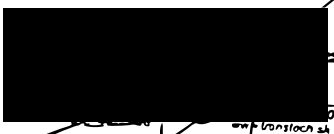
Názov položky:	Cena v eur bez DPH	Cena v eur s DPH
Jednorazové latexové rukavice v množstve 120 000ks (veľkosť S)	9 105,60	10 926,72
Jednorazové latexové rukavice v množstve 90 000ks (veľkosť M)	6 829,20	8 195,04
Jednorazové latexové rukavice v množstve 110 000ks (veľkosť L)	8 346,80	10 016,16
Všetky ostatné služby (ako napr. dovoz, manipulácia, atď.)	0	0
Cena spolu:	24 281,60	29 137,92

Platca/~~neplatea~~ DPH (nehodiace sa preškrtnite)

Čestné vyhlásenie: Predložením tejto ponuky zároveň **čestne vyhlasujem**, že postupujem v súlade s **etickým kódexom** uchádzača vydaným Úradom pre verejné obstarávanie:

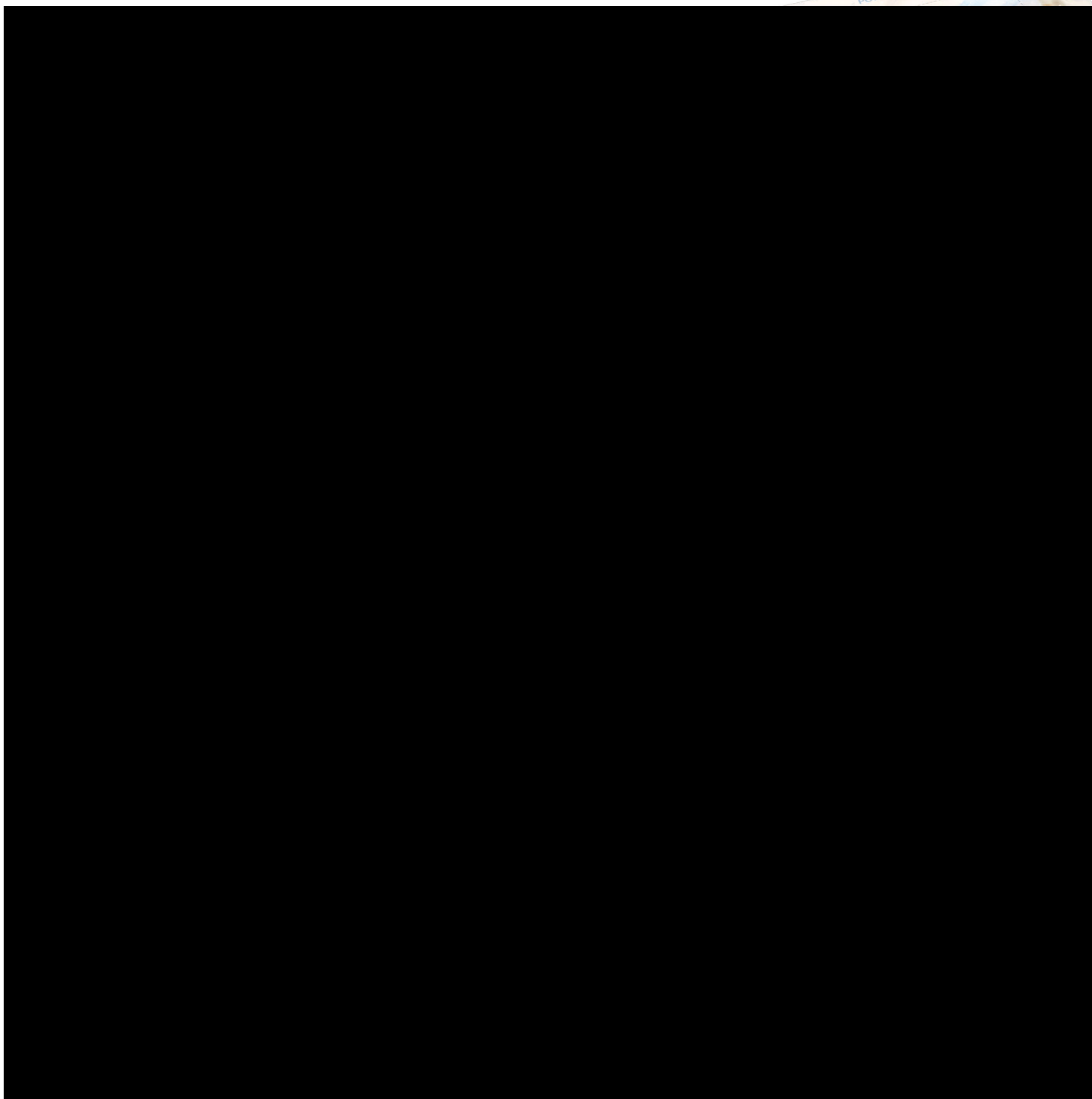
<https://www.uvo.gov.sk/zaujemcauchadzac/eticky-kodex-zaujemcu-uchadzaca-54b.html>

V Martine dňa 08.06.2021



pečiatka a podpis osoby oprávnenej
konať za uchádzača
Igor Pramuk, konateľ

LATEXOVÉ RUKAVICE ELITEX



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

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TECHNICKÝ LIST VÝROBKU

LATEXOVÉ RUKAVICE

ELITEX je značka rady latexových rukavic patriacich pod výrobcu:
PHOENIX Rubber Products



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

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LATEXOVÉ RUKAVICE ONE PLUS+1

Výrobca:

OnePlus Ambalaj
člen skupiny MENA GATE
Deposite iş Merkezi, A1 No:
310, Başakşehir/Istanbul
T: (+90) 212 671 00 54

Názov výrobku:

Latexové rukavice bez púdru

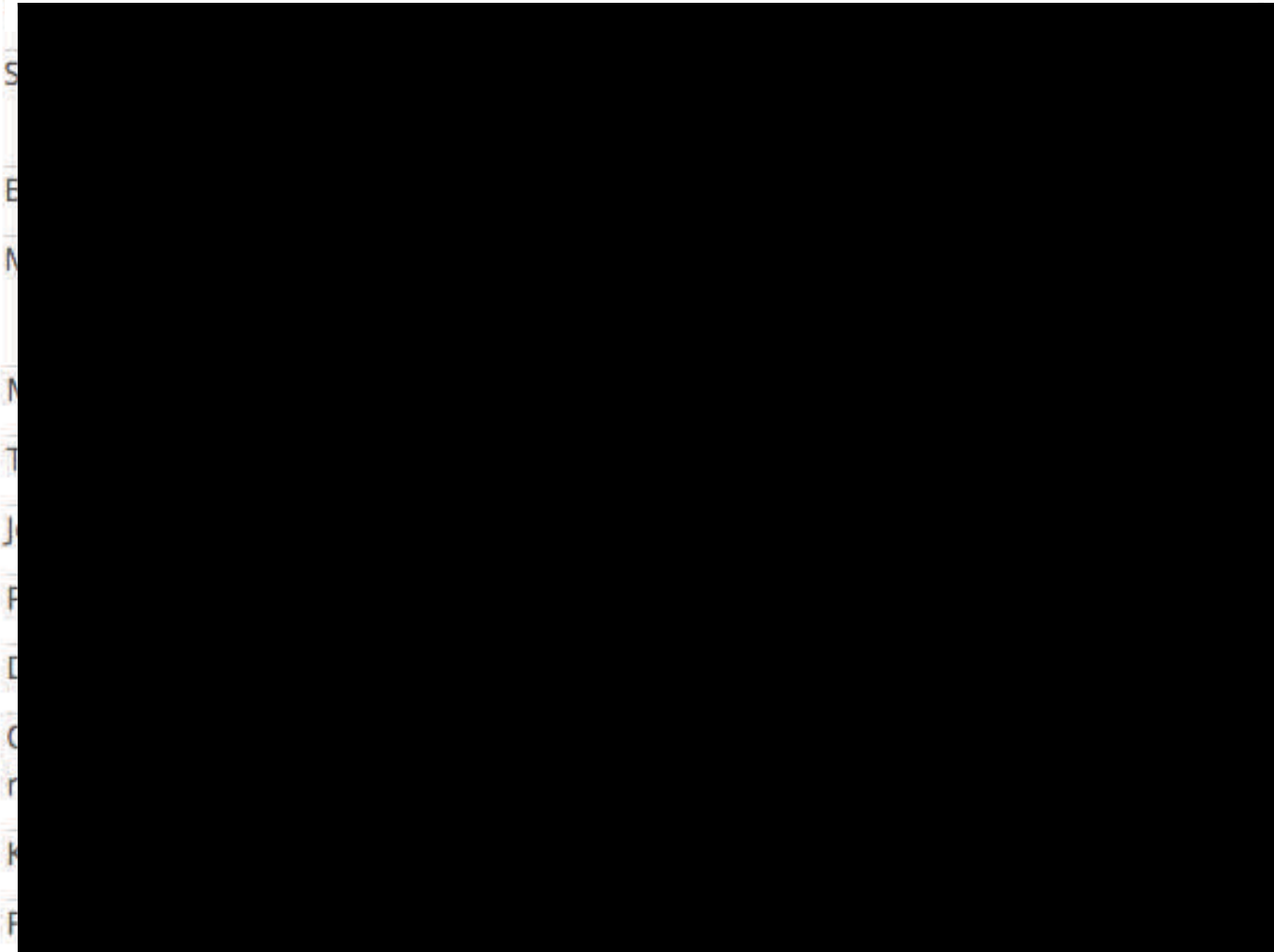


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LATEXOVÉ RUKAVICE

OnePlus je značka skupiny
MENA Gate



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STATUS S, s.r.o.,
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