

# glove@n Paloma

## Nitrile Exam Gloves Powder Free, Standard Cuff

To don **Paloma** is like putting on a second skin. Its absolute tactility commends it to delicate procedures and jobs plus an assured tensile strength and resistance to chemical expected of a nitrile glove. You owe it to yourself to try this exceptional nitrile glove from **GloveOn**.

	Clauson	Balance
Constant Constant	GloveOn	Patoma
Length (mm)		70
	≥ 2	30
Thickness Measurements (mm)		
Palm (centre of Palm)	0.07 ±	0.02
Finger (13mm ± 3mm from tip)	0.09 ±	0.02
Physical Properties	Before Ageing	After Ageing
Tensile Strength (MPa)	≥ 18	≥ 16
Elongation (%)	≥ 500	≥ 400
Inspection Levels & AQL	Inspection Level	AQL
Watertightness	G1	1.5
Physical Dimensions	S2	4.0
Physical Properties	S2	4.0
Visual Inspection (Major)	S4	2.5
Visual Inspection (Minor)	S4	4.0
Particulate Residue	N = 5	≤ 2mg/glove

Chemotherapy Drugs and Concentration (Tested for Resistance to Permeation by Chemotherapy Drugs as per ASTM 06978-05)	Minimum Breakthrough Detection Time Iminute			
Carmustine (BCNU), 3.3mg/ml (3,300 ppm)	16.2 minutes			
Cisplatin, 1.0mg/ml (1,000 ppm)	>240 minutes			
Cyclophosphamide (Cytoxan), 20.0mg/ml (20.000 ppm)	>240 minutes			
Dacarbazine (DTIC), 10.0mg/ml (10.000 ppm)	>240 minutes			
Doxorubicin Hydrochloride, 2.0mg/ml (2.000 ppm)	>240 minutes			
Etoposide (Toposar), 20.00mg/ml (20,000 ppm)	>240 minutes			
Fluorouracil, 50.0mg/ml (50,000 ppm)	>240 minutes			
Methotrexate, 25.0mg/ml (25,000 ppm)	>240 minutes			
Mitomycin C, 0.5mg/ml (500 ppm)	>240 minutes			
Paclitaxel (Taxol), 6.0mg/ml (6,000 ppm)	>240 minutes			
Thiotepa, 10.0mg/ml (10,000 ppm)	28.4 minutes			
Vincristine Sulfate, 1.0mg/ml (1,000 ppm)	>240 minutes			

WARNING. Carmustine and Thiotepa, at the tested concentration, degraded Paloma nitrite glove at 16.2 minutes and 28.4 minutes, respectively. The safe use of gloves in chemotherapy treatment is solely the decision of clinicians authorised to make such a decision.



Hartalega Sdn Bhd T: +603 6277 1733 E: info@hartalega.com.my



Visit us at gloveonglobal.com

#### FEATURES

- · Fingertip textured
- · Powder free
- · Not made with natural rubber latex
- Chemo drugs tested
- Lab chemical tested
- Ambidextrous
  - Violet blue colour

#### PACKAGING

100 gloves per box 10 boxes per carton

#### REGULATORY COMPLIANCE

FDA 510(k), MDD 93/42/EEC. REACH, ROHS Directive 2002/95/EC, EC 10/2011, EC 1935/2004

#### STANDARDS

ASTM D6319, ASTM D412, ASTM D573, ASTM D5151, ASTM D6124, EN455 part 1, 2, 3 & 4, EN 1186, EN 13130, CEN/TS 14234

#### MANUFACTURING ACCREDITATIONS

ISO 9001 ISO 13485 EN ISO 13485

## Certificate of CE-Registration

This is to certify that, in accordance with the Medical Device Directive 93/42/EEC, Medical Device Safety Service GmbH (MDSS) agrees to perform all duties and responsibilities as the Authorized Representative for:

#### Hartalega NGC Sdn. Bhd. No. 1, Persiaran Tanjung Kawasan Perindustrian Tanjung 43900 Sepang, Selangor MALAYSIA

as stipulated and demanded by the aforementioned Directive. The German Competent Authority has allocated the medical devices of the Manufacturer registration numbers as foreseen in:

#### Annex A dated January 18, 2019

The Manufacturer has provided MDSS with the appropriate Declaration(s) of Conformity confirming that the medical devices fulfill the applicable requirements of Directive 93/42/EEC. In compliance with German law, a safety officer has been appointed for Germany.

2019-01-18

President MDSS GmbH

MDSS · Medical Device Safety Service · Schiffgraben 41 · 30175 Hannover, Germany

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Medical Device Safety Service

\* 🛧 🕇

MDSS - Schiffgraben 41 - 30175 Hannover, Germany

Hartalega NGC Sdn. Bhd. Khairunnisa Warsito No. 1, Persiaran Tanjung Kawasan Perindustrian Tanjung 43900 Sepang, Selangor MALAYSIA Schiffgraben 41 30175 Hannover, Germany

Tel: + 49 - 511 - 62 62 86 30 Fox: + 49 - 511 - 62 62 86 33

> eMail: info@mdss.com Internet: www.mdss.com

> > 2019.01.18

#### Confirmation of CE Registration

Dear Khairunnisa,

It is our pleasure to enclose the new Certificate of CE-Registration for your product.

Please note that registration was performed under § 25 MPG (Medizinproduktegesetz). This is the *Federal Republic of Germany's national interpretation of Medical Device Directive 93/42/EEC.* Registration is therefore in accordance with EU legislation. We remind you that all products must meet the applicable provision of the European and national regulation before they may be placed on the market.

We are looking forward to continuing our good business relationship and wish you a successful product launch in Europe.

Best regards,

Juan Monferrer Tena Administrative Assistant Medical Device Safety Service GmbH

Encl. 1 Certificate of CE-Registration 1 Annex A

MDSS - Medical Device Safety Service GmbH Handelsregister Hannover HRB 57318 - USt-IdNr. DE 177346163 - Geschäftsführen Ludger Möller Bankverbindungen

Sparkosse Hannover S.W.I.F.T.: SPKHDE2H IBAN: DE24 2505 0180 0910 0792 77

Commerzbank AG, Honnover S.W.I.F.T.: COBADEFF 250 IBAN: DE67 2504 0066 0338 8816 00



UMDNS Code Description Notified Medical Device Product Name & Catalogue Number	Gloves, Examination/Treatment Latex Examination Gloves; Nitrile Examination Gloves;	Latex Examination Gloves; Nitrile Examination Gloves; Antimicrobial Nitrile Power Free Examination Gloves	Latex Powder Free Examination Gloves Latex Powdered Examination Gloves Nitrile Powder Free Examination Gloves Antimicrobial Nitrile Power Free Examination Gloves		
UMDNS	11-882				
Risk Class	-				
0	10				
Registration	DE/CA09/0170/H13/001-01				
NB No. / NB Certificate No.	NA				
NB Cert. Valid Until YYYY-MM-DD	NA				

Annex A dated January 18, 2019



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#### FDA Home<sup>3</sup> Medical Devices<sup>4</sup> Databases<sup>5</sup>

#### 510(K) Premarket Notification

for Hartalega

1 26 37 48 59 610 711 812 913 >14 10 results per page Export To Excel | New Search<sup>15</sup> Help16 Decision 510(K) Number +22 Applicant **Device Name** Date A17 A19 ¥18 ¥20 A23 ¥24 Powdered Sterile Latex Surgical Glove, With Protein Content Labeling HARTALEGA SDN BHD K001959 07/26/2000 Claim (200 Micrograms Or Less) Powder Free Sterile Latex Surgical Gloves, Contains 50 Microgram Or HARTALEGA SDN BHD K002593 11/29/2000 Less Of Total Water Extractable Protein Per Gram Freeform Blue Powderfree Nitrile HARTALEGA SDN BHD 11/18/2002 K022671 Examination Gloves Freeform Blue Powder-free Nitrile HARTALEGA SDN BHD 07/09/2004 K041391 Examination Gloves Nitrile Powder Free Examination HARTALEGA SDN BHD K050214 03/16/2005 Gloves (White) Nitrile Powdered Examination Gloves HARTALEGA SDN BHD K050215 03/11/2005 (White) **Chlorinated Powder Free Latex** HARTALEGA SDN BHD K050277 06/07/2005 Examination Gloves (Yellow) Nitrile Powder Free Examination HARTALEGA SDN BHD 08/12/2005 K051777 Gloves (Blue)

1 of 4

5/15/2020, 5:04 PM

#### FDA LIVE LINK

https://www.accessdata.fda.gov/cdrh\_docs/pdf18/K180505.PDF

https://fda.report/Company/HARTALEGA+SDN+BHD

## 510(k) Premarket Notification FDA Home Medical Devices Databases



510(k) | DeNovo | Registration & Listing | Adverse Events | Recalls | PMA | HDE | Classification | Standards CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

ew Search	Back To Search Res
Device Classification Name	Polymer Patient Examination Glove
510(K) Number	K133956
Device Name	NITRILE POWDER FREE EXAMINATION GLOVE WITH COLLOIDAL OATMEAL USP SKIN PROTECTANT DRUG - WHITE / DAWN BLUE / LEMON GREEN
Applicant	HARTALEGA SDN BHD NO. 7, KAWASAN PERUSAHAAN SURIA Bestari Jaya, Selangor, MY 45600
Applicant Contact	Nurul Aisyah Kong
Correspondent	HARTALEGA SDN BHD NO. 7, KAWASAN PERUSAHAAN SURIA Bestari Jaya, Selangor, MY 45600
Correspondent Contact	Nurul Aisyah Kong
Regulation Number	880.6250
Classification Product Code	LZA
Date Received	12/23/2013
Decision Date	05/28/2014
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Summary	Summary
Туре	Traditional
Reviewed By Third Party	No
Combination Product	No



Trade/Device Name: Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP with Low-Dermatitis Potential Claim and Tested For Use with Chemotherapy Drugs (White)

Regulation Number: 21 CFR 880.6250 Regulation Name: Patient Examination Glove Regulatory Class: Class I Product Code: LZA, LZC Dated: May 15, 2018 Received: May 17, 2018

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good

U.S. Food & Drug Administration 10903 New Hampshire Avenue Silver Spring, MD 20993 www.fda.pay manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <a href="http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm">http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm</a>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<u>https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/</u>) and CDRH Learn (<u>http://www.fda.gov/Training/CDRHLearn</u>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<u>http://www.fda.gov/DICE</u>) for more information or contact DICE by email (<u>DICE@fda.hhs.gov</u>) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

## Clarence W. Murray lii III -S

For Tina Kiang, Ph.D. Acting Director Division of Anesthesiology, General Hospital, Respiratory, Infection Control, and Dental Devices Office of Device Evaluation Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120

See PRA Statement below.

2010

#### Device Name

Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP with Low Dermatitis Potential Claim and Tested for Use with Chemotherapy Drugs (White)

#### Indications for Use (Describe)

Nitrile Powder Free Examination Glove with Colloidal Oatmeal USP with Low Dermatitis Potential Claim and Tested for Use with Chemotherapy Drugs (White) is a non-sterile disposable device intended for medical purpose that is worn on the examiner's hand to prevent contamination between patient and examiner. Is it also tested to be used against Chemotherapy Drugs.

The list of Chemotherapy Drugs tested (with breakthrough times) is as below;

Carmustine (3.3 mg/ml)	17.2 minutes
Cisplatin (1.0 mg/ml)	>240 minutes
Cyclophosphamide (20 mg/ml)	>240 minutes
Dacarbazine (10.0 mg/ml)	>240 minutes
Doxorubicin Hydrochloride (2.0 mg/ml)	>240 minutes
Etoposide (20 mg/ml)	>240 minutes
Fluorouracil (50 mg/m1)	>240 minutes
Methotrexate (25 mg/ml)	>240 minutes
Mitomycin C (0.5 mg/ml)	> 240 minutes
Paclitaxel (6.0 mg/ml)	> 240 minutes
Thiotepa (10.0 mg/ml)	36.1 minutes
Vincristine Sulfate (1.0 mg/ml)	>240 minutes

Do not use with Carmustine, Do not use with Thiotepa.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

XOver-The-Counter Use (21 CFR801 Subpart C)

#### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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FORM FDA 3881 (7117)

Page 1 of 1

THE Public org, Services (191) INC-3748. B



Testing. Development. Problem Solving.

April 15, 2009

## • TEST REPORT •

### PN 83672A - Amended

## CHEMICAL ANALYTICAL SERVICES

Prepared For: Hartalega SDN. BDH Ms. Nurul Aisyah Kong No. 7 Kawasan Perusahaan Suria Bestari Jaya Selangor, 45600 Malaysia

Prepared By iffany L Heller Chemical Technician

Approved By:

Ana C. Barbur, M.S. Manager, Chemical & Pharmaceutical Services

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### Testing. Development. Problem Solving.

April 15, 2009

Ms. Nurul Aisyah Kong Hartalega SDN. BHD

Page 1 of 3 - PN 83672A - Amended

Permeation testing per ASTM D 6978-05 on sample submitted by the above company. Wire SUBJECT: Transfer.

Glove sample identified as Nitrile Powder Free Examination Gloves (Blue) Code: ABLU. RECEIVED:

#### **TESTING CHEMOTHERAPY DRUGS:**

Table 1. List of the Testing Chemotherapy Drugs, Sources, and Expiration Dates

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Carmustine (BCNU)	Sigma; Lot# 038K4008; Expiration 12/2009
Cisplatin	Sigma; Lot# 59H3657; Expiration 09/2009
Cyclophosphamide (Cytoxan)	Sigma; Lot# 068K1131; Expiration 1/2010
Dacarbazine (DTIC)	Hospira; Lot# U022223AA; Expiration 06/2010
Doxorubicin Hydrochloride	Teva; Lot#07N625; Expiration 10/2009
Etoposide (Toposar)	Teva; Lot# 31303976B; Expiration 9/2011
Fluorouracil	APP; Lot# 203867; Expiration 03/2010
Mitomycin C	Sigma, Lot# 048K1086; Expiration 01/2010
Methotrexate	Hospira; Lot# U024457AA; Expiration 05/2010
Paclitaxel (Taxol)	Dabur Oncology; Lot# PA08H00701; Exp. 05/2010
Thiotepa	Sigma; Lot#078K1526; Expiration 12/2009
Vincristine Sulfate	Hospira, Lot# U037139AA; Expiration 12/2009

COLLECTION MEDIA: The collection media, which were selected, are listed in Table 2.

Table 2. Collection Media for Testing Chemotherapy Drugs

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Carmustine (BCNU), 3.3 mg/ml (3.300 ppm)	10% Ethanol Aqueous Solution
Cisplatin, 1.0 mg/ml (1,000 ppm)	Distilled Water
Cyclophosphamide (Cytoxan), 20 mg/ml (20,000 ppm)	Distilled Water
Dacarbazine (DTIC), 10.0 mg/ml (10,000 ppm)	Distilled Water
Doxorubicin Hydrochloride, 2.0 mg/ml (2,000 ppm)	Distilled Water
Etoposide (Toposar), 20.0 mg/ml (20,000 ppm)	Distilled Water
Fluorouracil, 50.0 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution
Methotrexate, 25 mg/ml (25,000 ppm)	Distilled Water
Mitomycin C, 0.5 mg/ml (500 ppm)	Distilled Water
Paclitaxel (Taxol), 6.0 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
Thiotepa, 10.0 mg/ml (10,000 ppm)	Distilled Water
Vincristine Sulfate, 1.0 mg/ml (1,000 ppm)	Distilled Water

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CRS REF : SAT/18/0248 DATE RECEIVED : MAR 02, 2018 DATE REPORTED: MAR 14, 2018 PAGE: 1 of 1

#### Report No. : CRSSA/02645/18

#### TEST REPORT

Product Description
Country of Origin
Size
Quantity Tested
Test Conducted
Test Method
Testing Period

Powder Free Nitrile Examination Gloves Malaysia Medium 200 pieces Freedom from holes EN455 Part 1/2000 02 Mar 2018 – 08 Mar 2018

Based on submitted samples, the following results -

Acceptable Quality Limit (AQL) : 1 -

Result

Note: Upon Custome. legally binding ds.  $_{\rm eff}$  been issued in more than one original. Only the first original is a  $_{\rm eff}$  be used for any legal purpose, including payment. (Original 1-3)

SGS (MALAYSIA) SDN. BHD.

CHEE TUCK CHOON B.Sc. MMIC SECTION HEAD

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SCS (Malaysia) Sdn. Bhd (Company No. 10871-7)

Lot 4. Persanan Jubi Persik, Sekayen 22, 40300 Shah Alam, Selangor, Malaysia 1 -6 (00) 5481 8282. F+6 (00) 5481 8215. www.sgs.com

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## **EC Declaration of Conformity**

#### We, the manufacturer

Hartalega NGC Sdn. Bhd., No. 1, Persiaran Tanjung, Kawasan Perindustrian Tanjung, 43900 Sepang, Selangor Darul Ehsan, Malaysia

#### with European Representative

Medical Device Safety Service (MDSS) Schiffgraben 41, 30175 Hannover, Germany

#### Declares that the new PPE described hereafter

Category III (Type C) HNGC-TF-PPE-002 Antimicrobial Nitrile Powder Free Examination Gloves Five fingered, chlorinated, powder free nitrile gloves, with textured fingers and beaded cuff. Thickness ≥2.2mil

#### is in conformity with the relevant Union harmonisation legislation

PPE Regulation (EU) 2016/425

where such is the case, with the national standard transposing harmonized standard number EN 420: 2003+A1: 2009 EN ISO 374 - 1:2016 EN ISO 374 - 5:2016

The notified body SATRA Technology Centre with Notified Body Number of 2777 performed the EU typeexamination (Module B) and issued the EU type-examination certificate 2777/11723-01/E00-00.

the PPE is subject to the conformity assessment procedure conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the Notified body SATRA Technology Centre with Notified Body Number of 2777.

Done at Hartalega NGC Sdn. Bhd. on 11th February 2020.

Kuan Eu Jin V Quality Management Representative

Hartalega Holdings Berhad (741883%) C-G-9, Jalan Dataran SD1, Dataran SD PJU 9 Bandar Sri Damansara 52200 Kuala Lumpur, Malaysia Tel: +603 - 6277 1733 - Fax: +603 - 6280 253 www.hartalega.com.my Hartalega NGC Sdn Bhd (184586-P) No. 1, Persiaran Tanjung Kawasan Perindustrian Tanjung 43900 Sepang, Selangor, Malaysia Tel: +603 - 8707 3000

Rev 01 Growing Global



**CRS REF : SAT/18/0248 DATE RECEIVED :** MAR 02, 2018 **DATE REPORTED:** MAR 14, 2018 **PAGE:** 1 of 1

#### Report No. : CRSSA/02646/18

#### TEST REPORT

Product Description	:	Powder Free Nitrile Examination Gloves
Country of Origin	:	Malaysia
Size	:	Medium
Quantity Tested	:	13 pieces
Test Conducted	:	Dimensions
Test Method	:	EN 455 Part 2:2015
Testing Period	:	02 Mar 2018 – 08 Mar 2018

Based on submitted samples, the following results obtained :-

Size	М	М	М	М	М	М	М	М	М	М	М	М	М	Median
Width	98	98	96	98	98	97	98	97	98	97	96	97	97	97
Length	250	255	250	255	251	250	252	252	250	254	252	253	252	252

Note: Upon Customer's request, this report has been issued in more than one original. Only the first original is a legally binding document and may be used for any legal purpose, including payment. (Original 1-3)

SGS (MALAYSIA) SDN. BHD.

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## UL Product **iQ**<sup>™</sup>

## QGWS.MH49134 - Protective Clothing and Ensembles for Emergency Medical Operations

## Protective Clothing and Ensembles for Emergency Medical Operations

See General Information for Protective Clothing and Ensembles for Emergency Medical Operations

#### HARTALEGA SDN BHD

C-G-9 Jalan Dataran Sd1 Dataran Sd Pju 9 Bandar Sri Damansara 52200 Kuala Lumpur, MALAYSIA Protective clothing, equipment and [C]BRN ensembles for emergency medical operations in accordance with NFPA 1999 (2018)

#### Single-use emergency medical examination gloves

Туре	Model/Style	UL Certification No.				
Nitrile	Glove On Maverick LC	49134010301				
Nitrile	HSB 41 (Orange) or GloveOn Vigor	49134010302				
Nitrile	HSB 45 (Black)	49134010303				
Nitrile	HSB 78 (Orange) or GloveOn Vigor LC	49134010304				
Nitrile	HSB 78 (Black) or GloveOn Hammer LC	49134010305				
Nitrile	HSB 71	49134010306				

Last Updated on 2019-12-23

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