



CERTIFICATES



phone number
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Merkez Mahallesi,
Güngören Cad. No:71/A
Bağcılar/İstanbul/Turkey



FDA CERTIFICATE





Certificate of Registration 2020

This is to certify that the registration of

BAYRAK 2023 BASKI MERKEZI SANAYI VE TICARET LIMITED SIRKETI

MERKEZ MAHALLESİ GÜNGÖREN CADDESİ NO: 71/A

ISTANBUL, TURKEY- 34164

with U.S. Food and Drug Administration as required by 21 CFR Part 807 is successfully completed by Liberty Management Group Ltd with the information provided by Bayrak 2023 Baski Merkezi Sanayi Ve Ticaret Limited Sirketi

Owner/Operator Number	10074433
Date of Registration	May 23, 2020
Date of Expiration	December 31, 2020
US Agent	Liberty Management Group Ltd.
Device Listing Numbers	See Annex
Certificate Number	3005230420

This certificate does not make representations or warranties to any person or entity other than the named certificate holder; it is issued for record keeping purpose only. This certificate does not denote endorsement or approval of certificate holder's facility or product by the U.S. food and Drug Administration. Liberty management Group Ltd. assumes no liability to any person or entity in connection with the foregoing.

The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Liberty Management Group Ltd. is not affiliated with the U.S. Food and Drug Administration.

LMG LIBERTY
MANAGEMENT
GROUP LTD.

75 Executive Drive, Aurora, Illinois, USA
www.fdahelp.us

A handwritten signature in black ink, reading "Manoj Zacharias", is located above the printed name.

Manoj Zacharias

President

Liberty Management Group LTD.

Dated: May 28, 2020



Certificate of Registration 2020

Annex - Device Listings

Listing Number	Code	Device Name - Proprietary Names
D404522	FXO	Suit, Surgical - OVERALL SUIT
D404523	OEA	Non-Surgical Isolation Gown - GOWN
D404519	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance - FACE MASK



CERTIFICATES





SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

This Certificate has been awarded to

**BAYRAK 2023 BASKI MERKEZİ
SAN. VE TİC. LTD. ŞTİ.**

MERKEZ MAH. GÜNGÖREN CAD. NO:71/A
BAĞCILAR / İSTANBUL / TÜRKİYE

In recognition of the organization's Managements System which complies with

ISO 9001:2015

The scope of activities covered by this certificate is defined below

PRODUCTION AND SALES OF SURGICAL APRON

CERRAHİ ÖNLÜK ÜRETİM VE SATIŞI

Certificate Number: SIS071021Q067

Date of Issue of Original Certificate: 07.10.2021

Date of Issue of Latest Certificate: 07.10.2021

Expiry Date: 06.10.2022

Re-Certification Due on: 07.09.2024



ACCREDITED
Management Systems
Certification Body

MSCB - 131



Managing Director



Note: This certificate is valid only if produced with the continuation letter after the surveillance is carried out successfully.

The Organization's documentation and Implementation has been reviewed and found to comply with the relevant standard rules. This certificate of Registration is based on the evaluation of the mentioned scope given above. Organization is responsible for maintaining the responsibilities of the relevant standard rules. Any significant changes in the scope of the certification or standard referred above render this certificate invalid. This is an accredited certificate issued by SIS Certifications Pvt. Ltd. sanctioned for issue by International Accreditation Services, 3060 Saturn Street Suite 100 Brea, California 92821-1732, USA.

Email us : support@siscertifications.com, info@siscertifications.co.in Call: - +91-9654721646
Web : - <http://www.siscertifications.co.in>, www.siscertifications.com
The status of this certificate can be verified on " <http://www.siscertifications.co.in>".



Certificate

**BAYRAK 2023 BASKI MERKEZİ
SAN. VE TİC. LTD. ŞTİ.**

**MERKEZ MAH. GÜNGÖREN CAD. NO:71/A
BAĞCILAR / İSTANBUL / TÜRKİYE**

Has been assessed and found to Comply with the Requirements of:

ISO 45001:2018

The Occupational Health and Safety Management System is applicable to:

PRODUCTION AND SALES OF PROTECTIVE FACE MASK

Certificate No: ISO/24665

Date of Certification Audit: 30.09.2021

Date of Issue: 07.10.2021

Date of Expiry: 06.10.2022

1st Surveillance Audit : September 2022

2nd Surveillance Audit : September 2023



Certificate of validity information E-mail: info@qscert.com
mail to confirm



SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

This Certificate has been awarded to

BAYRAK 2023 BASKI MERKEZİ SAN. VE TİC. LTD. ŞTİ.

MERKEZ MAH. GÜNGÖREN CAD. NO:71/A
BAĞCILAR / İSTANBUL / TÜRKİYE

In recognition of the organization's Managements System which complies with

ISO 14001:2015

The scope of activities covered by this certificate is defined below

MANUFACTURING AND SALES OF TEXTILE PRODUCTS

TEKSTİL ÜRÜNLERİ İMALATI VE SATIŞI

Certificate Number: SIS071021E068

Date of Issue of Orginal Certificate: 07.10.2021

Date of Issue of Latest Certificate: 07.10.2021

Expiry Date: 06.10.2022

Re-Certification Due on: 07.09.2024



ACCREDITED
Management Systems
Certification Body

MSCB - 131



Managing Director



Note: This certificate is valid only if produced with the continuation letter after the surveillance is carried out successfully.

The Organization's documentation and Implementation has been reviewed and found to comply with the relevant standard rules. This certificate of Registration is based on the evaluation of the mentioned scope given above. Organization is responsible for maintaining the responsibilities of the relevant standard rules. Any significant changes in the scope of the certification or standard referred above render this certificate invalid. This is an accredited certificate issued by SIS Certifications Pvt. Ltd. sanctioned for issue by International Accreditation Services, 3060 Saturn Street Suite 100 Brea, California 92821-1732, USA.

Email us : support@siscertifications.com, info@siscertifications.co.in Call: - +91-9654721646
Web : - <http://www.siscertifications.co.in>, www.siscertifications.com
The status of this certificate can be verified on " <http://www.siscertifications.co.in>".



Certificate

**BAYRAK 2023 BASKI MERKEZİ
SAN. VE TİC. LTD. ŞTİ.**

**MERKEZ MAH. GÜNGÖREN CAD. NO:71/A
BAĞCILAR / İSTANBUL / TÜRKİYE**

Has been assessed and found to Comply with the Requirements of:

**ISO 22716:2013:GMP
GOOD MANUFACTURING PRACTICES**

The GMP System is applicable to:

PRODUCTION AND SALES OF TEXTILE PRODUCTS

Certificate No: ISO/24666

Date of Certification Audit: 30.09.2021

Date of Issue: 07.10.2021

Date of Expiry: 06.10.2022

1st Surveillance Audit : September 2022

2nd Surveillance Audit : September 2023





SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

This Certificate has been awarded to

BAYRAK 2023 BASKI MERKEZİ SAN. VE TİC. LTD. ŞTİ.

MERKEZ MAH. GÜNGÖREN CAD. NO:71/A
BAĞCILAR / İSTANBUL / TÜRKİYE

In recognition of the organization's Management System
which complies with

ISO 13485:2016 (MD-QMS)

The scope of activities covered by this certificate is defined below

MANUFACTURING AND SALES OF TEXTILE PRODUCTS

TEKSTİL ÜRÜNLERİ İMALATI VE SATIŞI

SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

Certificate Number: **SIS071021MD069**

Date of Issue of Original Certificate: **07.10.2021**

Date of Issue of latest certificate: **07.10.2021**

Expiry Date: **06.10.2022**

Re-certification Due on: **07.09.2024**



We Do Not Sell, We Certify!

Managing Director



Note: This certificate is valid only if produced with the
continuation letter after the surveillance is carried out successfully.

The Organization's documentation and Implementation has been reviewed and found to comply with the relevant standard rules. This certificate of Registration is based on the evaluation of the mentioned scope given above. Organization is responsible for maintaining the responsibilities of the relevant standard rules. Any significant changes in the scope of the certification or standard referred above render this certificate invalid. This is an accredited certificate issued by SIS Certifications Pvt. Ltd. sanctioned for issue by International Organization for Accreditation Services, Burn point P.O. Box.293 St. George's, Grenada.

Corporate office(SIS): Unit No. 514, 5th Floor, Vipul Business Park, Sohna Road, Sector-48, Gurgaon-122018, Haryana, India.
International office(SIS):- URB. Santa Ana Cal. German, Scherieber 276, San Isidro, Lima, Peru 15047.
Email us :-support@siscertifications.com, info@siscertifications.co.in. Call:- +91 99105 01396, + 91 96430 73391
The status of this certificate can be verified on "http://www.siscertifications.com/verify/"
Web:- http://www.siscertifications.co.in, www.siscertifications.com



CE



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“medical products”



AB UYGUNLUK BEYANI

(2017/745/AB-Tıbbi Cihazlar Direktifi)

ÜRETİCİ FİRMA : BAYRAK 2023 BASKI MERKEZİ SANAYİ VE TİCARET LTD.ŞTİ

ADRES : Merkez Mah. Güngören Cad. No:71/A Bağcılar / İstanbul

Ürün Kapsamı : Tek Kullanımlık Steril Olmayan Kontaminasyon Önleyici Cerrahi Önlükler

MARKA : EFSANEMED

Ürün Tipleri

NON-STERİL TEK KULLANIMLIK CERRAHİ ÖNLÜK

NON-STERİL TEK KULLANIMLIK TAKVİYELİ CERRAHİ ÖNLÜK

Yukarıda tanımlanan ve CE işareti iliştilerilerek piyasaya arz edilen ürünün, ilgili AB direktifine göre üretildiğini ve direktifin gerektirdiği standartlara göre test edildiğini, tüm canlılara, insanlara, hayvanlara, bitkilere, çevreye, can ve mal güvenliğine zarar vermeyeceğini beyan ve taahhüt ederim.

SINIFLANDIRMA: Sınıf 1 (Steril ve ölçme fonksiyonu olmayan)

GMDN: 35091

TEMEL UDI-DI: 8682774453BYKUE

Standartlar

EN-ISO 13485:2016 Tıbbi Cihazlar - Kalite yönetim sistemleri - Yasal düzenleme gereksinimleri

EN ISO 14971: 2019 Tıbbi Cihazlar - Tıbbi Cihazlara risk yönetiminin uygulanması

ISO 15223-1:2016 Tıbbi Cihazlar - Tıbbi cihaz etiketleriyle kullanılacak simgeler, etiketleme ve sağlanacak bilgiler - Bölüm 1: Genel gereksinimler

Uygunluk Beyanı Başlangıç Tarihi: 01.06.2021

Üretici İmzası :

Şirket Yetkilisi

Habibe Veren

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"medikal ürünler"

BAYRAK 2023 BASKI MERKEZİ SAN.TİC.LTD.ŞTİ.
Merkez Mah. Güngören Cad.No:71/A Bağcılar/İSTANBUL
Tic. Sic. No: 27126530220 Gsm:0546 520 31 63 E-posta: info@efsanemed.com.tr
Web: www.efsanemed.com.tr Tic. Sic. No: 810803



DECLARATION OF CONFORMITY

(2017/745/EU - Medical Devices Directive)

MANUFACTURER : BAYRAK 2023 BASKI MERKEZİ SANAYİ VE TİCARET LTD ŞTİ

ADRESS : MERKEZ MAH. GÜNGÖREN CAD. NO: 71/A BAĞCILAR / İSTANBUL

PRODUCT SCOPE : Disposable Non-Sterile Non-Woven Bonnet

BRAND : EFSANEMED

PRODUCT TYPES

NON-STERIL DISPOSABLE NON-WOVEN BONNET

I hereby declare and undertake that the product described above and attached to the CE mark is manufactured in accordance with the relevant EU directive and tested in accordance with the standards required by the directive, and will not harm all livingbeings, humans, animals, plants, the environment, life and property safety and harm.

CLASSIFICATION: Class 1, Annex IV (without sterile and measuring function)
UDI-DI NUMBER: 868274453BYKUE

Standards

TS EN 14325
TS EN 464
TS EN ISO 6529
EN ISO 13485

Declaration of Conformity Start Date : 01/06/2021

Manufacturer Signature :

Sirket Yetkilisi
Habibe Veren

"medikal ürünler"
BAYRAK 2023 BASKI MERKEZİ SAN.TIC.LTD.ŞTİ.
Merkez Mah. Güngören Cad.No:71/A Bağcılar/İSTANBUL
Tel:0212 653 02 28 Gsm:0546 520 81 93 Eserler V.D. 1550552778
web: www.efsanemed.com Tic. Sicil No: 810803



DECLARATION OF CONFORMITY

(2017/745/EU - Medical Devices Directive)

MANUFACTURER : BAYRAK 2023 BASKI MERKEZİ SANAYİ VE TİCARET LTD ŞTİ
ADRESS : MERKEZ MAH. GÜNGÖREN CAD. NO: 71/A BAĞCILAR / İSTANBUL

PRODUCT SCOPE : Disposable Non-Sterile Overshoe

BRAND : EFSANEMED

Product Types

NON-STERIL DISPOSABLE OVERSHOE
NON-STERIL DISPOSABLE BOOT OVERSHOE
NON-STERIL DISPOSABLE OVERSHOEMATIC OVERSHOE

I hereby declare and undertake that the product described above and attached to the CE mark is manufactured in accordance with the relevant EU directive and tested in accordance with the standards required by the directive, and will not harm all living beings, humans, animals, plants, the environment, life and property safety and harm.

CLASSIFICATION : Class 1, Annex IV (without sterile and measuring function)

UDI-DI NUMBER : 868274453BYKUE

STANDARDS

TS EN ISO 20344
TS EN 13832-2
TS EN 13832-3

Declaration of Conformity Start Date : 01/06/2021

This text consists of 2 pages.

Manufacturer Signature :

Habibe Veren
Şirket Yetkilisi

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BAYRAK 2023 BASKI MERKEZİ SAN.TİC.LTD.ŞTİ.
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Web: www.efsanemed.com Tic. Sicil No: 810803

PRODUCT COD	PRODUCT NAME
YM30-01	GALOŞ (NAYLON – STD)
M06-10130-02	GALOŞ ÇİFT – KISA – LASTİKLİ – TABANLI
M06-10140-02	GALOŞ ÇİFT – KISA – LASTİKLİ – TABANLI
M06-10140-04	GALOŞ ÇİFT – UZUN – LASTİKLİ
M06-10257-02	GALOŞ ÇİFT – UZUN – LASTİKLİ

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BAYRAK 243 BASKI MERKEZİ SAN.TİC.LTD.ŞTİ.
Merkez Mah. Güngören Cad.No:71/A Bağcılar/İSTANBUL
Tel:0212 853 02 28 Gsm:0546 520 81 63 Eserler V.D 1550552778
web: www.efsanemed.com Tic Sicil No: 810803



DECLARATION OF CONFORMITY

(2017/745/EU - Medical Devices Directive)

MANUFACTURER : BAYRAK 2023 BASKI MERKEZİ SANAYİ VE TİCARET LTD ŞTİ
ADRESS : MERKEZ MAH. GÜNGÖREN CAD. NO: 71/A BAĞCILAR / İSTANBUL

PRODUCT SCOPE : Disposable Non-Sterile Anti-Contamination Surgical Gowns and Gynecology Gowns

BRAND : EFSANEMED

Product Types

NON-STERILE DISPOSABLE GYNECOLOGY SKIRT
NON-STERILE DISPOSABLE SLEEVELESS SURGICAL GARMENT

I hereby declare and undertake that the product described above and attached to the CE mark is manufactured in accordance with the relevant EU directive and tested in accordance with the standards required by the directive, and will not harm all living beings, humans, animals, plants, the environment, life and property safety and harm.

CLASSIFICATION : Class 1, Annex IV (without sterile and measuring function)

UDI-DI NUMBER : 868274453BYKUE

STANDARDS

TS EN ISO 20344
TS EN 13832-2
TS EN 13832-3

Declaration of Conformity Start Date : 01/06/2021

This text consists of 2 pages.

Manufacturer Signature :

Habibe Veren
Şirket Yetkilisi



BAYRAK 2023 BASKI MERKEZİ SAN. TİC. LTD. ŞTİ.
Merkez Mah. Güngören Cad. No: 71/A Bağcılar/İSTANBUL
Tel: 0212 853 02 28 GSM: 0546 520 81 63 E-posta: VD 1567652778
Web: www.efsanemed.com Tic. Sicil No: 810323

PRODUCT COD	PRODUCT NAME
M09-10440-01	NON-STERILE DISPOSABLE GYNECOLOGY SKIRT
M03-10440-12	NON-STERILE DISPOSABLE SLEEVELESS SURGICAL GARMENT

Pir ket yetkilisi
Habibe Veren

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BAYRAK 2003 PAZARI MERKEZİ SAN. TİC. LTD. ŞTİ.
Merkez: Mah. C. Gungören, Cad. No: 71/A, Beşiktaş / İSTANBUL
Tel: 0212 663 02 28 Gsm: 0546 620 61 63 E-posta: info@efsanemed.com.tr
Web: www.efsanemed.com Tic. Sic. No: 810803

EU TYPE EXAMINATION CERTIFICATE**Certificate No: 2163-PPE-1975****Bayrak 2023Baskı Merkezi San. Tic. Ltd. Şti.**

Merkez Mah. Güngören Caddesi No:71/A Bağcılar - İstanbul / TURKEY

It is certified that the manufacturer's technical file (Dated 04.01.2021) and the PPE product, detailed below, have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 based on the evaluation on technical documentation and relevant test reports.

Identification of the Personal Protective Equipment**Brand Name: EFSANEMED, Model: M2003**

Protective coverall manufactured from white air-permeable, laminated polypropylene non-woven fabric (55 gsm) with hood, inside overlock seams and seams are covered with blue hotmelt tape, elastic cuff, ankle and waist, zipper and zipper flap with double sided adhesive tape. The coverall is available in 6 nominal sizes.

For more details refer technical evaluation report provided to the manufacturer, dated 02.02.2021 and number 2163-KKD-1975.

The following harmonised standards have been applied:**EN ISO 13688:2013**, (General requirements for protective clothing)**EN 14605:2005+A1:2009**, (Chemical protective clothing protective performance against chemicals in the forms liquid and spray) Type 3 and Type 4, limited wear life clothing,**EN 14126:2003/AC:2004**, (Protective clothing against infective agents) for Type 3-B, Type 4-B,

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with the below requirements;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Ongoing successful performance in fulfilment of the requirements set out in **Personal Protective Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation

This certificate is initially issued on 02/02/2021 and will be valid for 5 years from the issue date.



Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director



EU TYPE EXAMINATION CERTIFICATE**Certificate No: 2163-PPE-1883****BAYRAK 2023 BASKI MERKEZİ SAN. TİC. LTD. ŞTİ.**
Merkez Mahallesi Güngören Caddesi No:71/A Bağcılar İstanbul TURKEY

It is certified that the manufacturer's technical file (Dated 14.11.2020) and the PPE product, detailed below, have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 based on the evaluation on technical documentation and relevant test reports.

Identification of the Personal Protective Equipment**Brand Name:** EFSANEMED, **Model:** M2002

Protective coverall manufactured from white laminated polypropylene non-woven fabric with hood, inside overlock seams, elastic cuff, ankle and waist, zipper and zipper flap. The coverall is available in 6 nominal sizes.

For more details refer technical evaluation report provided to the manufacturer, dated 08.01.2021 and number 2163-KKD-1883.

The following harmonised standards have been applied:

- EN ISO 13688:2013, (General requirements for protective clothing)
EN ISO 13982-1:2004/A1:2010, (Chemical protective clothing providing protection to the full body against airborne solid particulates) Type 5, limited wear life clothing,
EN 13034:2005+A1:2009, (Chemical protective clothing offering limited protective performance against liquid chemicals) Type 6, limited wear life clothing,
EN 14126:2003/AC:2004, (Protective clothing against infective agents) for Type 5-B, 6-B

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with the below requirements;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Ongoing successful performance in fulfilment of the requirements set out in **Personal Protective Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation

This certificate is initially issued on **08/01/2021** and will be valid for 5 years from the issue date.



Suat KACMAZ
UNIVERSAL CERTIFICATION
Director



EU DECLARATION OF CONFORMITY

MANUFACTURER

BAYRAK 2023 BASKI MERKEZİ SANAYİ VE TİCARET LİMİTED ŞİRKETİ

Merkez mah Güngören cad no: 71/ a bağcılar İstanbul /turkey

PRODUCT DESCRIPTION

Brand name: EFSANEMED , Model: M2002

Protective coverall manufactured from laminated polypropylene non-woven fabric with hood, inside over lock seams and seams are covered with adhesive tape, elastic cuff, ankle and waist, zipper and zipper flap. The coverall is available in 6 sizes.

Type 5 – Providing protection to the liquid chemicals in the form of jet

Type 6 – Providing protection to the liquid chemicals in the form of spray

Type 5-B, Type 6-B, Protective clothing against infective agents

The Manufacturer declares on his sole responsibility that the product above is, under conditions of normal use and conditions defined by the Manufacturer, safe and meets all the necessary legal

Conditions and requirements. The product is a personal protective equipment that is intended for single use and solely in accordance with the Manufacturer's instructions.

The conformity is assessed with the following mechanism:

- Complies with EU 2016/425 Personal Protective Equipment Regulation establishing technical requirements for Category III products,
- Complies with Technical harmonised standards in accordance the Essential Health and Safety Requirements referenced to EU 2016/425 PPE Regulation, EN ISO 13982-1:2004/A1:2010 , EN 14126:2009 , EN 13034:2005+A1:2009
- All required tests referred in above standards are conducted,
- Complies with other relevant harmonized legislation and community standards
- For the assessment of conformity the EU Type Examination certificate is issued, after all technical evaluations for conformity to the regulation and harmonised standards conducted under supervision of,
UNIVERSAL CERTIFICATION, SURVEILLANCE SERVICES and TRADE Co,
Notified Body number 2163

MARKING, LABELLING

Marking, labelling and user information are prepared in accordance with EU 2016/425 Personal Protective Equipment Regulation and EN 14126. The information is supplied with the product considering EN ISO 15223-1:2016 and EN 1041:2008+A1:2023.

MEASURES TO ENSURE CONFORMITY

The manufacturer declares that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and technical requirements for this type of product.

efsanemed
General Manager
Medikal Ürünler

BAYRAK 2023 BASKI MERKEZİ SAN.TİC.LTD.ŞTİ.
Merkez Mah. Güngören Cad No:71/A Bağcılar/İSTANBUL
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