



**MINISTERUL SĂNĂTĂȚII, MUNCII
ȘI PROTECȚIEI SOCIALE
AL REPUBLICII MOLDOVA**

МИНИСТЕРСТВО ЗДРАВООХРАНЕНИЯ, ТРУДА
И СОЦИАЛЬНОЙ ЗАЩИТЫ РЕСПУБЛИКИ МОЛДОВА

**AGENȚIA NAȚIONALĂ PENTRU SĂNĂTATE PUBLICĂ
НАЦИОНАЛЬНОЕ АГЕНТСТВО ОБЩЕСТВЕННОГО ЗДОРОВЬЯ**

MD-2028, muș. Chișinău, str. Gheorghe. Asachi, 67-a

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APROBAT DE MSMPS al RM / Утверждена МЗТСЗ РМ
31.10.11 Nr. 828

Centrul de Încercări de laborator acreditat de către
Centrul Național de Acreditare din Republica Moldova MOLDAC
Испытательный лабораторный центр аккредитованный
Национальным Аккредитационным Центром РМ MOLDAC
Certificat nr. LI-044 din 17.02.2018 valabil până la 16.02.2022
Acreditat în Sistemul Ministerului Sănătății, Muncii
și Protecției Sociale al RM
Аккредитованный в системе Министерства Здравоохранения, Труда и
Социальной Защиты Республики Молдова
Certificat nr. 2293 din 24.10.2014, valabil până la 24.10.2019

AVIZ SANITAR
PENTRU PRODUSELE ALIMENTARE ȘI NEALIMENTARE Nr.

Санитарное заключение для пищевых и непищевых продуктов

din/om " 08 "

octombrie

a./z. 2020

Prin prezentul aviz sanitar se confirmă că producerea, importul, utilizarea și desfacerea produselor / echipamentelor
Настоящим санитарным заключением подтверждается, что производство, ввоз, использование и реализация продукции / оборудования

Articole pentru igienă și întreținere m.c. Holder

anexa!

sunt conforme **Regulamentului (lor) sanitar (e) / соответствии санитарному (ым) регламенту (ам)** (se va indica
denumirea completă a Regulamentului (lor) sanitar (e) / указать полное наименование санитарного (ых) регламента (ов)

Regulamentului sanitar privind produsele cosmetice aprobat prin HG nr.1207 din 02.11.2016

Organizația-producătoare/importatoare, țara de origine / организация произв./импортёр, страна происхождения

Turcia, PAKTEN SAGLIK URUNLERI SAN.VE TIC. A.S.

Destinatarul avizului sanitar / получатель санитарного заключения

„TETIS INTERNATIONAL CO” SRL, Moldova, Chișinău, str. Calea Orheiului, 103/3

Ca temel pentru recunoașterea conformității produselor Regulamentului (lor) sanitar (e) menționat (e) a servit /
Основанием для признания продукции указанному (ым) санитарному (ым) регламенту (ам) послужило

Demers, contract f/n din 25.08.2020, facturi, certificate de calitate, rapoarte a încercărilor de laborator
nr.6239-6240 din 21.09.2020, din 28.09.2020

(a enumera documentele de însoțire, buletinele de analiză / перечислить сопроводительные док., протоколы исслед.)

Caracteristica sanitară a produselor / санитарная характеристика продукции:

Parametrii (factorii) / показатели (факторы)

Normativul sanitar / санитарный норматив

conform rapoartelor încercărilor de laborator nr.6239-6240 din 21.09.2020, din 28.09.2020

Domeniu de utilizare / Область применения:

întreținere

Condițiile necesare de utilizare, depozitare, transportare, măsurile de securitate / Необходимые условия
использования, хранения, транспортировки, меры безопасности:

importul, plasarea pe piață în condițiile respectării legislației în vigoare în Republica Moldova

AVIZUL SANITAR este valabil pină la / Санитарное Заключение действительно до: 30 octombrie 2021

DIRECTORUL AGENȚIEI NAȚIONALE PENTRU SĂNĂTATE PUBLICĂ

Int.

Vasile GUȘTIUC

(denumirea / Ф.И.О.)



ANSFHA03

0003711

03

ex: St. Constantinovici
tel: 574 679*

Anexa la aviz sanitar

Denumirea produsului	Producator	Tara producatorului
Holder scutece pentru maturi in asortiment	Pakten	Turcia
Holder chiloti-scutece pentru maturi in asortiment	Pakten	Turcia
Holder aleze igienice in asortiment	Pakten	Turcia

Director interimar



Vasile GUȘTIUC

PAKTEN SAĞLIK ÜRÜNLERİ SAN. ve TIC. A.Ş
2. Organize Sanayi Bölgesi
83221 No'lu Cadde
No: 9 27120 Baspınar / Gaziantep
Turkey

Muenster, 16.06.2017

Dermatological expertise on a
four-week clinical-dermatological
application test

HOLDER ADULT DIAPERS

Client:	PAKTEN SAĞLIK ÜRÜNLERİ SAN. ve TIC. A.Ş 2. Organize Sanayi Bölgesi 83221 No'lu Cadde No: 9 27120 Baspınar / Gaziantep Turkey
Test persons:	20 female and male panellists with healthy skin
Test period:	4 weeks
Test area:	intimate area
Application frequency:	several times a day

1. PRINCIPLE AND METHOD

The purpose of this study was to examine the tolerability of **HOLDER ADULT DIAPERS** according to clinical-dermatological test criteria. The participants were able to consult the physicians taking care of the test participants any day in case of any objective or subjective skin changes were noted.

Before the commencement of the trial, all participants were dermatologically examined.

Only subjects without any pathological skin disorders were included in the test group.

Each of the participants was instructed to use the product for the duration of four weeks several times daily.

2. PANELLISTS

The test panel does include 20 female and male panellists.

2.1 INCLUSION CRITERIA

- Subjects with healthy skin in the test area aged 18 years and older

2.2 EXCLUSION CRITERIA

- severe or chronic skin inflammation
- serious inner or chronic diseases
- intake of drugs that possibly can interfere with skin reactions (Glucocorticoids, antiallergics, topical immuno modulator, etc.)
- application of pharmaceutical products and skin care products with active ingredients until 7-10 days before testing
- severe allergies or occurred severe side effects after usage of cosmetic products
- sunbath or usage of tanning bed during the study period
- known cancer
- pregnancy or lactation period

2. 3 SUBJECTS

No.	Initials	Gender	Age	Skin type
1.	AcIl	f	65	dry/sensitive
2.	CzEv	f	36	dry
3.	SiCl	f	44	dry
4.	FeBa	f	61	dry
5.	GaJo	f	41	dry/sensitive
6.	GrRi	f	72	dry/sensitive
7.	HaAl	f	88	combination
8.	HaUt	f	64	dry/sensitive
9.	JuMa	f	72	normal
10.	JuMi	f	51	normal
11.	KaSa	f	44	dry/sensitive
12.	KlJu	f	49	normal
13.	MiAn	f	61	normal
14.	MoMa	f	64	dry
15.	MüUl	f	38	dry/sensitive
16.	RaCh	f	53	dry/sensitive
17.	RiMa	f	62	dry
18.	RoTa	f	40	dry
19.	ScRu	f	54	very dry
20.	SoAn	f	51	normal/sensitive

- ⋮ Application Test
- ⋮ HOLDER ADULT DIAPERS

3. DERMATOLOGICAL EXAMINATIONS

1. At the beginning of the study

All of the participants were determined to have healthy skin by dermatological standard and criteria. No pathological skin disorder was detected.

2. During the study

No complaint of any pathological skin disorder was reported during the course of this four-week application test. Interruptions of the application test and/or medical intervention were not necessary.

3. At the end of the study

During the final dermatological examination at the end of the study, none of the participants showed development of any pathological skin disorder in the test area. The mentioned product was well-tolerated, no evidence of any pathological skin disorder could be detected.

4. DERMATOLOGICAL ASSESSMENT CRITERIA

1. Erythema
2. Scaling
3. Dryness

- ⋮ Application Test
- ⋮ HOLDER ADULT DIAPERS

5. ASSESSMENT OF RESULTS

All of the 20 study participants tolerated the product **HOLDER ADULT DIAPERS** very well during the course of the four-week application test under dermatological and clinical criteria. There were no undesired or even pathological reactions in the test area.

It can, therefore, be concluded that the use of **HOLDER ADULT DIAPERS** in practice do not lead to any undesired skin reactions due to any skin irritant or sensitizing characteristics of the product.

From a dermatological point of view it can hence be
concluded that the product
HOLDER ADULT DIAPERS
was tolerated
very well
in a four-week application test under
clinical-dermatological conditions.

Dr. med. Werner Voss
Specialist in Dermatology,
Venereology, Allergology,
Phlebology and
Environmental Medicine



Dr. med. Gerrit Schlippe
Specialist in Dermatology
and Venereology



THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

TSE has issued an IQNet recognized certificate that the organization:

PAKTEN SAĞLIK ÜRÜNLERİ SAN. VE TİC. A.Ş.

2. OSB 83221 NOLU CAD. NO:9 BAŞPINAR -
GAZİANTEP / TÜRKİYE

has implemented and maintains a
QUALITY MANAGEMENT SYSTEM

which fulfills the requirements of the following standard:

TS EN ISO 9001:2015

Issued on: 02-04-2019

Expires on: 24-03-2022

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number : TR-KY-6732/13-R15



Alex Stoichitoiu
President of IQNet

Gökçen Bircan Değerliyurt
Head of System Certification Group

*IQNet Partners**

AENOR Spain AFNOR Certification France APCER Portugal CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany FCAV Brazil
FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE - SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.



THE INTERNATIONAL CERTIFICATION NETWORK

Annex to IQNET Certificate Number :TR-KY-6732/13-R15

Name and Address of the certified organization

PAKTEN SAĞLIK ÜRÜNLERİ SAN. VE TİC. A.Ş.

2. OSB 83221 NOLU CAD. NO:9 BAŞPINAR - GAZİANTEP / TÜRKİYE

Scope of the Certificate

MANUFACTURES AND SALES OF

- BABY DIAPER
- ADULT DIAPER
- WET WIPES
- BABY SHAMPOO
- LIQUID SOAP
- BABY DIAPER CHANGING MAT
- BED SHEET

This annex is only valid in connection with the above-mentioned certificate

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TURKISH STANDARDS INSTITUTION





KALİTE YÖNETİM SİSTEMİ BELGESİ

QUALITY MANAGEMENT SYSTEM CERTIFICATE



TÜRK STANDARDLARI ENSTİTÜSÜ
bu belge ile

PAKTEN SAĞLIK ÜRÜNLERİ SAN. VE TİC. A.Ş.
2. OSB 83221 NOLU CAD. NO:9 BAŞPINAR -
GAZİANTEP / TÜRKİYE

TURKISH STANDARDS INSTITUTION
hereby certifies that the organization

PAKTEN SAĞLIK ÜRÜNLERİ SAN. VE TİC. A.Ş.
2. OSB 83221 NOLU CAD. NO:9 BAŞPINAR -
GAZİANTEP / TÜRKİYE



kuruluşunun TS EN ISO 9001:2015 şartlarına uygun bir KALİTE
YÖNETİM SİSTEMİNE sahip olduğunu onaylar.

has a QUALITY MANAGEMENT SYSTEM which fulfills
the requirements of the TS EN ISO 9001:2015

Belge kapsamı Ek'te verilmiştir

TÜRK STANDARDLARI ENSTİTÜSÜ
TURKISH STANDARDS INSTITUTION

Scope of the certificate is given in annex



Bu belge belgelendirme şartlarına
uygunluk sağlandığı sürece geçerlidir.

SİSTEM BELGELENDİRME GRUP BAŞKANI
HEAD of SYSTEM CERTIFICATION GROUP

GÖKCEN BİRCAN DEĞERLİYURT

Türk Standardları Enstitüsü Türk Akreditasyon Kurumu TÜRKAK tarafından akredite edilmiştir.
Turkish Standards Institution, has been accredited by the Turkish Accreditation Agency TÜRKAK.

Belge No / Certificate No

KY-6732/13-R15

Belge Tarihi / Date of Certificate

02.04.2019

Geçerlilik Tarihi / Valid Until

24.03.2022

Revizyon Tarihi / Date of Revision

02.04.2019

İlk Belge Tarihi / Initial Certification Date

19.03.2013

This certificate is valid provided that compliance
with the certification requirement is maintained.



KALİTE YÖNETİM SİSTEMİ BELGESİ

QUALITY MANAGEMENT SYSTEM CERTIFICATE

EK / APPENDIX



Belge No / Certificate No: **KY-6732/13-R15**

Belgeli Kuruluş Adı, Adresi:

Name and Address of the Certified Organization:

Belge Tarihi / Date of Certificate: **02.04.2019**

PAKTEN SAĞLIK ÜRÜNLERİ SAN. VE TİC. A.Ş.
2. OSB 83221 NOLU CAD. NO:9 BAŞPINAR -
GAZİANTEP / TÜRKİYE



Belge Kapsamı:

TS EN ISO 9001:2015

- ÇOCUK BEZİ
- HASTA BEZİ
- ISLAK HAVLU
- BEBE ŞAMPUANI
- SIVI SABUN
- BEBEK BAKIM ÖRTÜSÜ
- YATAK KORUYUCU ÖRTÜSÜ

ÜRETİMİ VE SATIŞI

Scope of the Certificate:

TS EN ISO 9001:2015

MANUFACTURES AND SALES OF

- BABY DIAPER
- ADULT DIAPER
- WET WIPES
- BABY SHAMPOO
- LIQUID SOAP
- BABY DIAPER CHANGING MAT
- BED SHEET



Ofertant: Tetis International Co SRL

FOTO produselor oferite:



Holder Scutece p/u adulti Large N30



Holder Scutece p/u adulti Medium N30



Holder Scutece p/u adulti XLarge N30