



# CERTIFICATE

BossCert certifies that the management system of the organization has been assessed and found to be in accordance with the requirements of the related standard.

## ISO 14001:2015

### ARKAN GRUP SAĞLIK ÜRÜNLERİ ANONİM ŞİRKETİ

HQ-MERKEZ: Kocatepe Mah. Gümrük İskelesi Cad. Mega Center Apt.  
No:89/ 893 BAYRAMPAŞA İSTANBUL TÜRKİYE

FACTORY-FABRİKA: Velimeşe Mah. Hacı Şeremet Cad. No:14  
ERGENE TEKİRDAĞ

BEBEK BEZİ, HASTA BEZİ, HİJYENİK KADIN PEDİ, ISLAK MENDİL, BEBEK ŞAMPUANI, BEBEK  
LOSYONU, BEBEK YAĞI ÜRÜNLERİNİN ÜRETİMİ VE SATIŞI

MANUFACTURE AND MARKETING OF BABY DIAPER, ADULT DIAPER, SANITARY NAPKINS,  
WET WIPE, BABY SHAMPOO, BABY LOTION AND BABY OIL PRODUCTS

Certification No : 105ATE005  
Initial Certificate Date : 15.09.2017  
Issue Date/ Revision Date-No: 21.09.2022- REV:05  
Valid Period : 21.09.2022- 14.09.2023  
Expiration Date : 14.09.2023

General Manager





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## ISO 22716:2007 GMP

COSMETICS- GOOD MANUFACTURING PRACTICES (GMP)

### ARKAN GRUP SAĞLIK ÜRÜNLERİ ANONİM ŞİRKETİ

HQ-MERKEZ: Kocatepe Mah. Gümrük İskelesi Cad. Mega Center Apt.  
No:89/ 893 BAYRAMPAŞA İSTANBUL TÜRKİYE

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BEBEK BEZİ, HASTA BEZİ, HİJYENİK KADIN PEDİ, ISLAK MENDİL, BEBEK ŞAMPUANI, BEBEK LOSYONU, BEBEK YAĞI ÜRÜNLERİNİN ÜRETİMİ VE SATIŞI

MANUFACTURE AND MARKETING OF BABY DIAPER, ADULT DIAPER, SANITARY NAPKINS, WET WIPE, BABY SHAMPOO, BABY LOTION AND BABY OIL PRODUCTS

Certification No : 189ATG016  
Initial Certificate Date : 11.10.2018  
Issue Date/ Revision Date-No: 21.09.2022- REV:04  
Valid Period : 21.09.2022- 10.10.2023  
Expiration Date : 10.10.2024

General Manager





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## ISO 45001:2018

### ARKAN GRUP SAĞLIK ÜRÜNLERİ ANONİM ŞİRKETİ

HQ-MERKEZ: Kocatepe Mah. Gümrük İskelesi Cad. Mega Center Apt.  
No:89/ 893 BAYRAMPAŞA İSTANBUL TÜRKİYE

FACTORY-FABRİKA: Velimeşe Mah. Hacı Şeremet Cad. No:14  
ERGENE TEKİRDAĞ

BEBEK BEZİ, HASTA BEZİ, HİJYENİK KADIN PEDİ, ISLAK MENDİL, BEBEK ŞAMPUANI, BEBEK LOSYONU, BEBEK YAĞI ÜRÜNLERİNİN ÜRETİMİ VE SATIŞI

MANUFACTURE AND MARKETING OF BABY DIAPER, ADULT DIAPER, SANITARY NAPKINS,  
WET WIPE, BABY SHAMPOO, BABY LOTION AND BABY OIL PRODUCTS

Certification No : 105ATO005  
Initial Certificate Date : 15.09.2017  
Issue Date/ Revision Date-No : 21.09.2022- REV:05  
Valid Period : 21.09.2022- 14.09.2023  
Expiration Date : 14.09.2023

General Manager



# G-CERTI *certificate*

*hereby certifies that*

## ARKAN GRUP SAĞLIK ÜRÜNLERİ ANONİM ŞİRKETİ

Merkez : Kocatepe Mah. Gümrük İskelesi Cad. Mega Center Apt.

No:89/ 893 BAYRAMPAŞA İSTANBUL TÜRKİYE

Fabrika : Velimeşe Mah. Hacı Şeremet Cad. No:14 ERGENE TEKİRDAĞ  
TÜRKİYE

*meets the Standard Requirements & Scope as following*

ISO 9001:2015 *Quality Management Systems*

**BEBEK BEZİ, HASTA BEZİ, HİJYENİK KADIN PEDİ, ISLAK MENDİL,  
BEBEK ŞAMPUANI, BEBEK LOSYONU, BEBEK YAĞI ÜRÜNLERİNİN  
ÜRETİMİ VE SATIŞI**

MANUFACTURE AND MARKETING OF BABY DIAPER, ADULT DIAPER,  
SANITARY NAPKINS, WET WIPE, BABY SHAMPOO, BABY LOTION AND  
BABY OIL PRODUCTS

Certificate No : GCTB-0109-QC

Initial Date : 2017. 09. 15

Issue Date : 2022. 09. 21

Expiry Date : 2023. 09. 14

Valid period : 2022. 09. 21 ~ 2023. 09. 14

Signed for and on behalf of GCERTI  
President I.K.Choi



To verify the validity of this certificate please visit : [www.gcerti.com](http://www.gcerti.com)  
Korea, Seoul, Eunpyeong-gu, Eunpyeong-ro, 88, 15F. Surveillance  
audits shall be conducted at least once a calendar year, except in  
recertification years. This is to certify that the Management Systems  
of this company has been found to confirm to the above. If the certified  
client does not allow surveillance, recertification audits, certificate should  
be returned to GCERTI. This certificate remains the property of GCERTI  
and this certificate is recognized by GCERTI.





## EC DECLARATION OF CONFORMITY

(EU) No. 2017/745 Regulations of the European Parliament & Council

**Company Name** : Arkan Grup Sağlık Ürünleri A.Ş.  
**SRN Code** : Not Received yet.  
**EMDN Code** : T04010103  
**Auth. Person / Title** : Özcan Arkan / General Manager  
**Address** : *Velimeşe Mah. Hacı Şeremet Cad. NO:14 Ergene Tekirdag*  
**Phone** : (+90) 282-676-46 83  
**Web/Mail** : [www.pine.com.tr](http://www.pine.com.tr)

**Description of Product / Product Part** : Adult Diaper  
**Product Trademarks** : Dermaped  
**Product Type** : Given Annex1

**PRODUCTION SITE** : Arkan Grup Sağlık Ürünleri A.Ş.  
Velimeşe Mah. Hacı Şeremet Cad. NO:14  
Ergene Tekirdag  
(+90) 282-676-46 83  
[www.pine.com.tr](http://www.pine.com.tr)

**Classification:** : Class I Other (Without Measuring Function, Non-Sterile, Not Reusable)  
Annex VIII, Rule 1

**Conformity assessment route** : Arkan Grup Sağlık Ürünleri A.Ş. uses the following procedures for the CE-labelling of their products according the Regulation MDR 2017/745:  
Class I non-sterile: EC conformity declaration according to annex IV of the Regulation MDR 2017/745 for medical devices.

**Harmonized Standards** : EN ISO 13485:2016 , EN ISO 14971:2019 , CEN ISO/TR 24971:2020  
EN ISO 20417:2021 , EN 15223-1:2021, EN 13795-1:2019 , EN ISO 10993-1:2020  
EN ISO 10993-5:2009,EN ISO 10993-10:2013

This Declaration of conformity is issued only, under responsibility of Arkan Grup Sağlık Ürünleri A.Ş. Medical device (s) listed in Annex-1 and Annex-2, related to Medical devices (EU) MDR 2017/745 We declare that it meets the provision of the regulation. This statement is being supported by quality system approval ISO 13485, given by IGC (Certificate No : 23-B-0587) all supporting documents stored at Manufacturer's premises.

This declaration is edited according to (EU) No. 2017/745 EUROPEAN PARLIAMENT and COUNCIL STATEMENT Annex IV. EU Declaration of conformity.

**First CE Marking Date** : 20.01.2022  
**Declaration Date** : 20.01.2022  
**Declaration Place** : Tekirdađ, TURKIYE  
**Declared by** : Özcan ARKAN  
**Signature** : 

**Annex.1**

Product Name	Product Type	Packaging	Barcode Code	Basic-UDI	GMDN Code
Dermaped Yetiřkin Hasta Alt Bezi	Küçük	19 pcs	8699096966127	869909696HB86	11239
Dermaped Yetiřkin Hasta Alt Bezi	Orta	17 pvs	8699096966134	869909696HB86	11239
Dermaped Yetiřkin Hasta Alt Bezi	Büyük	15 pcs	8699096966141	869909696HB86	11239
Dermaped Yetiřkin Hasta Alt Bezi	Ekstra Büyük	13 pcs	8699096966158	869909696HB86	11239
Dermaped Yetiřkin Hasta Alt Bezi	Küçük	30 pcs	8699096966011	869909696HB86	11239
Dermaped Yetiřkin Hasta Alt Bezi	Orta	30 pcs	8699096966028	869909696HB86	11239
Dermaped Yetiřkin Hasta Alt Bezi	Büyük	30 pcs	8699096966035	869909696HB86	11239
Dermaped Yetiřkin Hasta Alt Bezi	Ekstra Büyük	30 pcs	8699096966042	869909696HB86	11239