



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

Child.





CERTIFICATE

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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

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

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

General Manager

Expiration Date : 10.10.2024





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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
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.



ACCREDITED
Management Systems
Certification Body
MSCB-113





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

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

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 to 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 : Tekirdağ, TURKIYE
Declared by : Özcan ARKAN
Signature : 

Annex.1

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