

Anexa nr. 1  
La Procedurile administrative pentru notificarea  
dispozitivelor medicale care dețin marcajul CE

Către Agenția Medicamentului  
și Dispozitivelor Medicale

**NOTIFICARE**

pentru înregistrarea dispozitivelor medicale în Registrul de stat  
al dispozitivelor medicale  
nr. 04 din 08.09.2023

Solicitantul „**MedGlobalFarm**” SRL, cu sediul **R.Moldova, mun.Chisinau, str.Miron Costin 17/7, of.71**, tel./fax: 022-523090, e-mail [medglobalfarm@mail.ru](mailto:medglobalfarm@mail.ru), solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
		Scutece-adulți L	Dermaped Large	Dermaped Large	47783
		Scutece-adulți M	Dermaped Medium	Dermaped Medium	47783
		Scutece-adulți S	Dermaped Small	Dermaped Small	47783
		Scutece-adulți XL	Dermaped X-Large	Dermaped X-Large	47783
		Scutece-copii 2-5kg	1 Pine Newborn	1 Pine Newborn	47783
		Scutece-copii 4-9kg	3 Pine Midi	3 Pine Midi	47783
		Scutece-copii 7-14kg	4 Pine Maxi	4 Pine Maxi	47783

Se anexează următoarele acte:

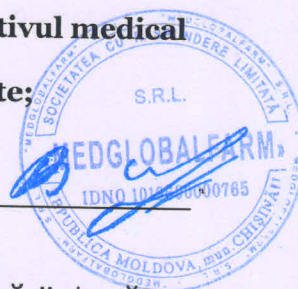
**declarația de conformitate CE emisă de producător pentru dispozitivul medical fabricat;**

**certificatul de conformitate CE valabil pentru dispozitivele fabricate;**

**actul prin care producătorul își desemnează reprezentantul/**

Data 08.09.2023

Semnătura



**Tabelul de recepționare a notificării**

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele; prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	





## CE DECLARATION OF CONFORMITY

We here with declare, as Manufacturer;

That the following described products in our delivered version complies with the appropriate basic safety and health requirements of the 98/79/EC (In Vitro Diagnostic Medical Devices). In case of alteration of the product, not agreed upon by us, this declaration will lose its validity.

**ÜRETİCİ FİRMA:** Arkan Grup Sağlık Ürünleri A.Ş.

Velimeşe Mah. Hacı Şeremet Cad. No: 14 Ergene Tekirdağ TURKEY

### Applicable EC Directives

Directive 98/79/EC

### Applicable Technical Standarts

ISO 9001:2015

ISO 13485:2016

**Signature Date** : 30.05.2023

**Effective Date** : 30.05.2026

8699096965472	Pine Pants	Maxi	48
8699096965489	Pine Pants	Junior	46
8699096965496	Pine Pants	Extra Large	44
8699096965502	Pine Pants	Maxi	18
8699096965519	Pine Pants	Junior	17
8699096965526	Pine Pants	Extra Large	16
8699096964017	Pine Soft	Newborn	54
8699096964024	Pine Soft	Mini	52
8699096964031	Pine Soft	Midi	42
8699096964048	Pine Soft	Maxi	36
8699096964055	Pine Soft	Junior	28





# CE

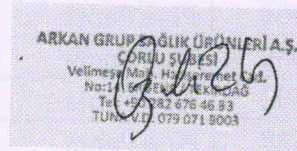


8699096964062	Pine Soft	Extra Large	22
8699096964079	Pine Soft	Maxi Plus	32
8699096964086	Pine Soft	Junior Plus	26
8699096964093	Pine Soft	XX Large	16
8699096964116	Pine Soft	Newborn	81
8699096964123	Pine Soft	Mini	102
8699096964130	Pine Soft	Midi	84
8699096964147	Pine Soft	Maxi	72
8699096964154	Pine Soft	Junior	56
8699096964161	Pine Soft	Extra Large	44
8699096964178	Pine Soft	Maxi Plus	64
8699096964185	Pine Soft	Junior Plus	52
8699096964369	Pine Classic	Mini	26
8699096964376	Pine Classic	Midi	22
8699096964383	Pine Classic	Maxi	20
8699096964390	Pine Classic	Junior	16
8699096964406	Pine Classic	Extra Large	14
8699096964420	Pine Classic	Mini	87
8699096964437	Pine Classic	Midi	78
8699096964444	Pine Classic	Maxi	68
8699096964451	Pine Classic	Junior	58
8699096964468	Pine Classic	Extra Large	48



*[Handwritten signature]*

Özlem Uras  
Quality Manager







**EC DECLARATION OF CONFORMITY**  
**(EU) No. 2017/745 Regulations of the European Parliament & Council**

**Company Name** : Arkan Grup Sağlık Ürünleri A.Ş.  
**SRN Code** : TR-MF-000027138  
**EMDN Code** : T04010103  
**Auth. Person / Title** : Özcan Arkan /General Manager  
**Address** : Velimeşe Mah. Hacı Şeremet Cad. No: 14 Ergene Tekirdağ  
**Phone** : (+90) 282-676-46 83  
**Web/Mail** : www.pine.com.tr

**Description of Product / Product Part** : Patient Diaper  
**Product Trademarks** : Pine/Dermaped  
**Product Type** : Various Sizes

**PRODUCTION SITE 1** : Arkan Grup Sağlık Ürünleri A.Ş.  
Velimeşe Mah. Hacı Şeremet Cad. No: 14 Ergene Tekirdağ  
(+90) 282-676-46 83  
[www.pine.com.tr](http://www.pine.com.tr)

**Compliance Directives:**  
2017/745 Regulations of the European Parliament & Council

**Harmonized Standards:**  
EN ISO 13485: 2016 / EN ISO 14971: 2019 / ISO TR 24971: 2020 / EN 15223-1: 2021 / EN ISO 20417:2021  
Manufactured according to harmonized standards.

**Product Class Information:**  
2017/745 Regulations of the European Parliament & Council (Annex VIII, Rule 1)  
We declare that it complies with the provisions of Class I Other (No measurement function, non-sterile, non-reusable).



This Declaration of conformity is issued only, under responsibility of **Arkan Grup Sağlık Ürünleri A.Ş.**  
Medical device (s) listed in Annex-1, 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 **Institute of Global Certification** all supporting documents stored at Manufacturer's premises.

TD.EC.02 / Rev.03 / 17.05.2023

03





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

Our Pine and Dermaped branded products, whose product names, codes, models and Basic-UDI codes are given below;

REF CODE	PRODUCT NAME	BRAND	PRODUCT TYPE	PACKAGING	BARCODE NO	BASIC UDI	GMDN CODE	PRODUCTION SITE
ADSM-P30	Adult Diaper	Pine	Small	30 PCS	8699096960804	869909696HB86	11239	1
ADMD-P30	Adult Diaper	Pine	Medium	30 PCS	8699096960637	869909696HB86	11239	1
ADLG-P30	Adult Diaper	Pine	Large	30 PCS	8699096960644	869909696HB86	11239	1
ADXL-P30	Adult Diaper	Pine	XLarge	30 PCS	8699096961078	869909696HB86	11239	1
PNSM-P30	Adult Diaper	Pine	Small	30 PCS	8699096966059	869909696HB86	11239	1
PNMD-P30	Adult Diaper	Pine	Medium	30 PCS	8699096966066	869909696HB86	11239	1
PNLG-P30	Adult Diaper	Pine	Large	30 PCS	8699096966073	869909696HB86	11239	1
PNXL-P30	Adult Diaper	Pine	XLarge	30 PCS	8699096966080	869909696HB86	11239	1
ADMD-P09	Adult Diaper	Pine	Medium	9 PCS	8699096960613	869909696HB86	11239	1
ADLG-P07	Adult Diaper	Pine	Large	7 PCS	8699096960620	869909696HB86	11239	1
AP-M10	Adult Diaper Pants	Pine	Medium	10 PCS	8699096960811	869909696HB86	11239	1,2,3,4
AP-L8	Adult Diaper Pants	Pine	Large	8 PCS	8699096960828	869909696HB86	11239	1,2,3,4
AP-XL7	Adult Diaper Pants	Pine	XLarge	7 PCS	8699096960835	869909696HB86	11239	1,2,3,4
AP-M30	Adult Diaper Pants	Pine	Medium	30 PCS	8699096960880	869909696HB86	11239	1,2,3,4
AP-L30	Adult Diaper Pants	Pine	Large	30 PCS	8699096960897	869909696HB86	11239	1,2,3,4
AP-XL30	Adult Diaper Pants	Pine	XLarge	30 PCS	8699096960903	869909696HB86	11239	1,2,3,4
DPSM-P30	Adult Diaper	Dermaped	Small	30 PCS	8699096966011	869909696HB86	11239	1
REF CODE	PRODUCT NAME	BRAND	PRODUCT TYPE	PACKAGING	BARCODE NO	BASIC UDI	GMDN CODE	PRODUCTION SITE
DPMD-P30	Adult Diaper	Dermaped	Medium	30 PCS	8699096966028	869909696HB86	11239	1
DPLG-P30	Adult Diaper	Dermaped	Large	30 PCS	8699096966035	869909696HB86	11239	1
DPXL-P30	Adult Diaper	Dermaped	XLarge	30 PCS	8699096966042	869909696HB86	11239	1
DPSM-P19	Adult Diaper	Dermaped	Small	19 PCS	8699096966127	869909696HB86	11239	1
DPMD-P17	Adult Diaper	Dermaped	Medium	17 PCS	8699096966134	869909696HB86	11239	1
DPLG-P15	Adult Diaper	Dermaped	Large	15 PCS	8699096966141	869909696HB86	11239	1



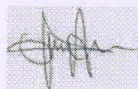


DPXL-P13	Adult Diaper	Dermaped	XLarge	13 PCS	8699096966158	869909696HB86	11239	1
----------	--------------	----------	--------	--------	---------------	---------------	-------	---

**Table 1. Product List**

**First CE Marking Date** : 20.01.2022  
**Declaration Date** : 17.05.2023  
**Declaration Place** : İstanbul, Türkiye  
**Declared by** : Özcan ARKAN

**Signature** :








# CERTIFICATE

## EC UYGUNLUK BEYANI (Ec Declaration Of Conformity)

**MANUFACTURER**

**NAME :** ARKAN GRUP SAĞLIK ÜRÜNLERİ ANONİM ŞİRKETİ

**ADDRESS :** ŞAHİNTEPE MAH. ŞEHİT POLİS FETHİ SEKİN CAD. İGTOT (İSTANBUL GIDA TOPTANCILAR ÇARŞISI) 13.BLOK NO: 1 Y İÇ KAPI NO: 10 BAŞAKŞEHİR/ İSTANBUL

THAT THE FOLLOWING DESCRIBED IN OUR DELIVERED VERSION COMPLIES WITH APPROPRIATE BASIC SAFETY AND HEALTH REQUIREMENTS BASES ON 93/42/EEC ON ITS DESIGN AND TYPE, AS BROUGHT INTO CIRCULATION BY US. IN CASE OF ALTERATION OF THE PRODUCT, NOT AGREED UPON BY US, THIS DECLARATION WILL LOSE ITS VALIDITY

**PRODUCT NAME:**

BEBEK BEZİ / BABY DIAPER

**PRODUCT BRAND:**

PINE, DERMAPED, HONEY BEBİŞH

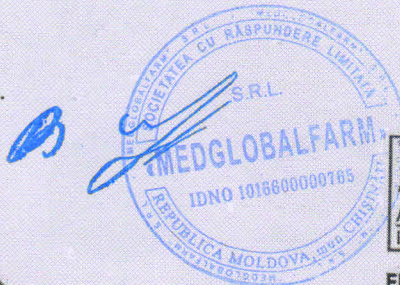
**RELATED DIRECTIVES:**

93/42/EEC

**Regulations Applied according to HARMONIZE STANDARDS:**

TS OIC /SMİIC 15

**CLASSIFICATIONS** : CLASS  
**CERTIFICATE NUMBER** : 202018199  
**CERTIFICATE CODE** : ARKAN  
**CERTIFICATE ISSUE DATE** : 21.08.2023  
**CERTIFICATE VALIDITY DATE** : 21.08.2024



00649

**Ekol Belgelendirme Şirketi**

Maslak Mah. Maslak Meydan Sokak Beybi Giz Plaza No.1 Kat.15 D.55  
Sarıyer / İstanbul / Türkiye Tel. +90 212 909 12 07 [www.ekolbelgelendirme.com](http://www.ekolbelgelendirme.com)

Belgenin geçerlilik durumu <https://www.ekolbelgelendirme.com/sertifikaara/> adresinden kontrol edilebilir.





# CERTIFICATE

## EC UYGUNLUK BEYANI (Ec Declaration Of Conformity)

### MANUFACTURER

NAME : ARKAN GRUP SAĞLIK ÜRÜNLERİ ANONİM ŞİRKETİ

ADDRESS : ŞAHİNTEPE MAH. ŞEHİT POLİS FETHİ SEKİN CAD. İGTOT (İSTANBUL GIDA TOPTANCILAR ÇARŞISI) 13.BLOK NO: 1 Y İÇ KAPI NO: 10 BAŞAKŞEHİR/ İSTANBUL

THAT THE FOLLOWING DESCRIBED IN OUR DELIVERED VERSION COMPLIES WITH APPROPRIATE BASIC SAFETY AND HEALTH REQUIREMENTS BASES ON 93/42/EEC ON ITS DESIGN AND TYPE, AS BROUGHT INTO CIRCULATION BY US. IN CASE OF ALTERATION OF THE PRODUCT, NOT AGREED UPON BY US, THIS DECLARATION WILL LOSE ITS VALIDITY

### PRODUCT NAME:

HASTA BEZİ / PATIENT DIAPER

### PRODUCT BRAND:

PINE, DERMAPED, HONEY BEBİSH

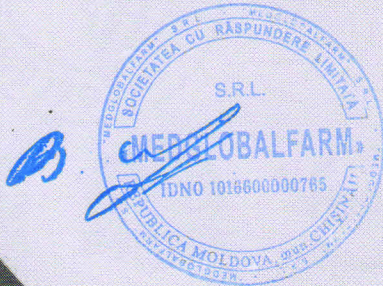
### RELATED DIRECTIVES:

93/42/EEC

Regulations Applied according to HARMONIZE STANDARDS:

TS OIC /SMIIC 15

CLASSIFICATIONS : CLASS  
CERTIFICATE NUMBER : 202018200  
CERTIFICATE CODE : ARKAN  
CERTIFICATE ISSUE DATE : 21.08.2023  
CERTIFICATE VALIDITY DATE : 21.08.2024



00650

Ekol Belgelendirme Şirketi

Maslak Mah. Maslak Meydan Sokak Beybi Giz Plaza No.1 Kat.15 D.55  
Sarıyer / İstanbul / Türkiye Tel. +90 212 909 12 07 www.ekolbelgelendirme.com

Belgenin geçerlilik durumu <https://www.ekolbelgelendirme.com/sertifikaara/> adresinden kontrol edilebilir.



# pine



August 15, 2023

## LETTER OF AUTHORIZATION

To whom may it concern. We declare that MED GLOBALFARM SRL located at address bellow:

Str.Miron Costin 17/7, of.71, Chisinau,

is our distributor and it is authorized to import the products from ARKAN GRUP Sağlık Ürünleri A.Ş.

located at bellow address:

Velimeşe Mah. Hacı Şeremet Cad. No: 14 Ergene Tekirdağ, TÜRKİYE  
to Moldova territory.

In addition, we hereby authorize MED GLOBALFARM SRL to register our products the Republic of Moldova.

This authorization is effective from 15th August 2023 and will be valid until 1st September 2024.

Your sincerely,

General Manager:

Özcan Arkan

ARKAN GRUP SAĞLIK  
ÜRÜNLERİ A.Ş.  
Bağcıbaşı Şiş. Sağlık Pine Light Beşin Cad.  
10/101 (İstanbul Güneş Toplantı Merkezi) - İST.  
S. Blok No: 11 K. Kat: No: 10/101 - İST.  
Tic. Sicil No: 279917/11



pine.com.tr

Merkez Ofis:  
Tekstilkent Koza Plaza  
A Blok Kat: 25 No: 94  
Esentepe - İstanbul/TR

Fabrika:  
Velimeşe Mah.  
Hacı Şeremet Cad. No:14  
Ergene - Tekirdağ/TR

Merkez:  
Kocatepe Mah. Gümrük İskelesi Cad.  
Mega Center No: 89/893  
Bayrampaşa - İstanbul/TR

Vergi Dairesi: Tuna  
Vergi No: 079 071 8003  
Ticaret Sicil No: 526908-0

Tel : +90 212 438 76 01  
Faks : +90 212 438 76 04  
E-mail: info@pine.com.tr



Către Agenția Medicamentului și Dispozitive Medicale

**DECLARAȚIE PE PROPRIE RĂSPUNDERE**

Solicitant: Medglobalfarm SRL, cu sediul mun. Chișinău, str. Miron Costin  
17/7, of. 71,

declar pe proprie răspundere, cunoscând prevederile art. 352<sup>1</sup>, Codul Penal al  
Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate  
pentru notificarea dispozitivului medical:

Scutece-adulți L

Scutece-adulți M

Scutece-adulți S

Scutece-adulți XL

Scutece-copii 2-5kg

Scutece-copii 4-9kg

Scutece-copii 7-14kg

**Sunt autentice și corespund realității.**

Director general Granaci Boris



Semnătura

Data 08.09.2023