



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 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