



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,Underpad
Product Trademarks : Dermaped
Product Type : Given Annex1
PRODUCTION SITE :

Arkan Grup Sağlık Ürünleri A.Ş.
Velimeşe Mah. Hacı Şeremet Cad. NO:14
Ergene Tekirdag
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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 : Tekirdağ, TURKIYE

Declared by : Özcan ARKAN

Signature :