

İMALATÇI/MANUFACTURER : **HONNES SAĞLIK VE ENDÜSTRİYEL ÜRÜNLERİ A.Ş.**

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SINIFLANDIRMA : **AB 2017/745 Kural I, Sınıf-1 diğer (steril ve ölçme fonksiyonu olmayan)**
CLASSIFICATION **EU 2017/745 Medical Device Regulation-CLASS I**

UYGUNLUK DEĞERLENDİRME : **EU 2017/745 Tıbbi Cihaz Direktifi-**
CONFIRMITY ASSESMENT **EK II & III-AT Uygunluk Beyanı**
EU 2017/745 Medical Device Regulation
Annex II & III per article 52.7

ÜRÜN ADI / PRODUCT NAME : **B-good Cerrahi Maske / Surgical Mask**

ÜRÜN ADI/PRODUCT NAME	GMDN KODU/GMDN CODE	GMDN ADI/GMDN NAME
Cerrahi Maske Surgical Mask	35177	Maske, cerrahi, tek kullanımlık Mask, Surgical, Single use

KULLANIM AMACI / PURPOSE OF USE :

Hijyen gerekli uygulamaların hepsinde kullanılabilir. Doktorlarınve hastaların kullanımın uygundur. Nonwoven kumaştan üretilmiştir. Burun kısmındaki ayarlanabilir tel sayesinde yüze uyum sağlayarak tam koruma sağlar. Esnek ve yumuşaktır. Hava geçirgen yapısı sayesinde nefes almayı kolaylaştırır. 3 katlı yapıya sahiptir. *Can be used in all hygiene applications. Suitable for doctors and patients use. Made of non-woven fabric. With adjustable nose clip, it provides full protection. It is flexible and soft. Air permeable structure allows easy breathing. It has 3 ply.*

AB 2017/745 UYGUNLUK BEYANI
EU DECLARATION OF CONFORMITY

	Description	EAN-13
GCMS10	Freedom IIR Black A02.3 PACK10	5600899440724
BCM02S	Freedom IIR Black A02.2 PACK50	5600899440717
BCM02	Freedom IIR Basic A02.1 PACK50	5600899440700

YUKARIDA TANIMLI ÜRÜNÜN, TALİMATLAR KURULU TIBBİ CİHAZLAR KARARNAMESİ EU 2017/745 İÇİN GEREKLİ ŞARTLARA UYGUN OLDUĞUNU BEYAN EDERİZ. DESTEKLEYİCİ TÜM BELGELER ÜRETİCİNİN TESİSLERİNDE BULUNMAKTADIR.

WE HEREWITH DECLARE THAT THE ATTACHED *PRODUCT* MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE EU 2017/745 FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

By way of exception, instructions for use shall not be required for class I and class IIa devices if such devices can be used safely without any such instructions.

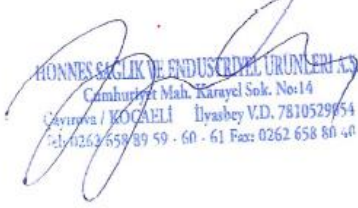
İLGİLİ STANDARTLAR / STANDARTS APPLIED :

EN ISO 13485	Medical devices-Quality management systems - Requirements for regulatory purposes
EN ISO 15223-1	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied
2017 / 745	Medical Device Regulation
EN ISO 1041	Information supplied by the manufacturer of medical devices
EN ISO 14683:2019+AC:2019	Medical face masks - Requirements and test methods
EN ISO 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 14971	Medical devices - Application of risk management to medical devices
EN ISO 10993	Biological evaluation of medical devices

Authorised Signatory

Name-Surname : Serdar AĞALAR

Position : Assistant Genaral Manager

Signed : 
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