



**ALMİ MEDİKAL**

## **2017/745 EU Medical Devices Directive Declaration Of Conformity**

ALMİ MEDİKAL VE ÖZEL HEALTH HZ.LTD.ŞTİ. As a company, we declare under our sole responsibility that the devices covered by this declaration comply with the Regulation (EU) 2017/745 of the European Parliament and of the Council on Medical Devices and that the requirements specified in the Regulation are fulfilled for these devices.

<b>Manufacturer</b>	ALMİ MEDİKAL VEÖZEL SAĞLIK HZ.LTD.ŞTİ.
<b>Adress</b>	Anbar Mah. Demirciler San. Sitesi 22 Cad No: 15 Melikgazi /KAYSERİ
<b>Products names</b>	Cover, Patient Gown, Bone, Inspection Gown, rectoscopic shorts , Shoe Cover, Mask.
<b>Katalog/Referans No</b>	<b>Cover:</b> 1A400600 <b>Patient Gown:</b> 1A400200 <b>Bone:</b> 1A400800 <b>Inspection Gown:</b> 1A400300 <b>Rectoscopic shorts:</b> 1A401200 <b>Shoe Cover :</b> 1A400900 <b>Mask:</b> 1A400700
<b>Kullanım Amacı</b>	<p><b>Cover:</b> It is used during the examination, it is disposable. It is a multi-purpose protective clothing made of natural, synthetic or a combination of these materials, which is sometimes worn over short dresses by physicians during the examination of the patient. It may not be liquid resistant or water permeable depending on the intended purpose of the vehicle. An examination gown is used during patient examination procedures to protect both the patient and the physician from contamination by microorganisms or bodily fluids. This garment is disposable.</p> <p><b>Patient Gown:</b> It is a multi-purpose protective clothing made of natural, synthetic or a combination of these materials, which is sometimes worn over short dresses by physicians during the examination of the patient. It may not be liquid resistant or water permeable depending on the intended purpose of the vehicle. An examination gown is used during patient examination procedures to protect both the patient and the physician from contamination by microorganisms or bodily fluids. This garment is disposable. The patient is dressed during treatment.</p> <p><b>Bone :</b> It is used by physicians, nurses etc. during the examination, it is disposable. It is used for the purpose of protecting both the patient and the physician from the contamination of microorganisms or body fluids during patient examination procedures, which allows health professionals to work comfortably, prevents contamination, absorbs liquids such as sweat, and is made of disposable Nonwoven fabric.</p> <p><b>Patient Gown:</b> A multi-purpose protective clothing made of natural, synthetic or a combination of these materials, sometimes worn over short dresses by physicians during the examination of</p>

	<p>the patient. It may not be liquid resistant or water permeable depending on the intended purpose of the vehicle.</p> <p>An examination gown is used during patient examination procedures to protect both the patient and the physician from contamination by microorganisms or bodily fluids. This garment is disposable. It is dressed to the patient during the treatment, it is disposable.</p> <p><b>Rectoscopic shorts:</b> The patient is dressed during the examination, It is used to protect both the patient and the physician from the contamination of microorganisms or body fluids during examination and treatment, during patient examination procedures, which ensures easy and comfortable examination and treatment procedures.</p> <p><b>Shoe Cover:</b> Shoe covers are worn over shoes when entering hygiene-important areas and places where examination and therapeutic procedures are performed. It is disposable. It is used to protect the entered environment. It is used to prevent contamination from outside.</p> <p><b>Mask:</b> It is used by physicians, nurses, etc. during the examination, and is disposable.</p>												
<b>BARCODES</b>	<p><b>Cover</b> :86999139193501</p> <p><b>Patient Gown</b> :86999139191521</p> <p><b>Bone</b> :86999139194591</p> <p><b>Inspection Gown</b> :86999139192061</p> <p><b>Rectoscopic shorts</b> :86999139196571</p> <p><b>Shoe Cover</b> : 869991391 9602</p> <p><b>Mask</b> : 86999139194041</p>												
<b>Class Specification</b>	<b>CLASS-I</b>												
<b>Conformity Assessment Procedure (Attachments carried out in the product assessment are marked).</b>	<table> <tr> <td><input type="checkbox"/></td><td>ANNEX-IV (Annex II &amp; III)</td></tr> <tr> <td>X</td><td>Declaration of conformity</td></tr> <tr> <td><input type="checkbox"/></td><td>ANNEX-IX (CHAPTER I &amp; III)</td></tr> <tr> <td><input type="checkbox"/></td><td>Quality management system</td></tr> <tr> <td><input type="checkbox"/></td><td>ANNEX-IX (PART II)</td></tr> <tr> <td><input type="checkbox"/></td><td>Technical Documentation Mod.</td></tr> </table>	<input type="checkbox"/>	ANNEX-IV (Annex II & III)	X	Declaration of conformity	<input type="checkbox"/>	ANNEX-IX (CHAPTER I & III)	<input type="checkbox"/>	Quality management system	<input type="checkbox"/>	ANNEX-IX (PART II)	<input type="checkbox"/>	Technical Documentation Mod.
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**İmza Tarihi ve Yeri** : 20.01.2022 / KAYSERİ

**İmzalayan** : Dr.Mithat ALTUNTAŞ

**Görevi** : General Manager



