



ALMI MEDİKAL

2017/745 EU Medical Devices Directive Declaration Of Conformity

ALMI 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.

Manufacturer	ALMI MEDİKAL VEÖZEL SAĞLIK HZ.LTD.ŞTİ.
Adress	Anbar Mah. Demirciler San. Sitesi 22 Cad No: 15 Melikgazi /KAYSERİ
Products names	Cover, Patient Gown, Bone, Inspection Gown, rectoscopic shorts , Shoe Cover, Mask.
Katalog/Referans No	Cover: 1A400600 Patient Gown: 1A400200 Bone: 1A400800 Inspection Gown: 1A400300 Rectoscopic shorts: 1A401200 Shoe Cover : 1A400900 Mask: 1A400700
Kullanım Amacı	Cover: 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. Patient Gown: 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. Bone : 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. Patient Gown: 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

	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. It is dressed to the patient during the treatment, it is disposable. Rectoscopic shorts: 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. Shoe Cover: 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. Mask: It is used by physicians, nurses, etc. during the examination, and is disposable.												
BARCODES	Cover :86999139193501 Patient Gown :86999139191521 Bone :86999139194591 Inspection Gown :86999139192061 Rectoscopic shorts :86999139196571 Shoe Cover : 869991391 9602 Mask : 86999139194041												
Class Specification	CLASS-I												
Conformity Assessment Procedure (Attachments carried out in the product assessment are marked).	<table> <tr> <td>☐</td><td>ANNEX-IV (Annex II & III)</td></tr> <tr> <td>X</td><td>Declaration of conformity</td></tr> <tr> <td>☐</td><td>ANNEX-IX (CHAPTER I & III)</td></tr> <tr> <td>☐</td><td>Quality management system</td></tr> <tr> <td>☐</td><td>ANNEX-IX (PART II)</td></tr> <tr> <td>☐</td><td>Technical Documentation Mod.</td></tr> </table>	☐	ANNEX-IV (Annex II & III)	X	Declaration of conformity	☐	ANNEX-IX (CHAPTER I & III)	☐	Quality management system	☐	ANNEX-IX (PART II)	☐	Technical Documentation Mod.
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İmza Tarihi ve Yeri : 20.01.2022 / KAYSERİ

İmzalayan : Dr.Mithat ALTUNTAŞ

Görevi : General Manager



