Lloyd's Register

Certificate of Approval

This is to certify that the Management System of:

PMS TIBBİ CİHAZLAR TEKNOLOJİSİ SAN. VE TİC. A.Ş.

Karaduvar Mah. Serbest Bölge, 11. Cad. No: 46 Akdeniz, 33020 Mersin, Turkey

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 0030762

The scope of this approval is applicable to:
ISO 13485:2016
Design, Development, Production, Marketing And Sales of Sterilisation Packages, Wrapping Materials, Chemical Indicators, Autoclave Tapes, Bowie-Dick Test Packs, Autoclavable Biohazard Bags, Autoclavable Biohazard Bags with Cardboard Inlay (Class I- Other)

Paul Graaf

Area Operations Manager, Europe

Issued by: LRQA France SAS

for and on behalf of: Lloyd's Register Quality Assurance Limited

UKAS
MANAGEMENT
SYSTEMS
0001

Current issue date: 9 November 2021 Original approval(s):
Expiry date: 17 October 2024 ISO 9001 - 22 November 2009
Certificate identity number: 10404173

Certificate of Approval

This is to certify that the Management System of:

PMS TIBBİ CİHAZLAR TEKNOLOJİSİ SAN. VE TİC. A.Ş.

Karaduvar Mah. Serbest Bölge, 11. Cad. No: 46 Akdeniz, 33020 Mersin, Turkey

has been approved by Lloyd's Register to the following standards:

ISO 9001:2015

Approval number(s): ISO 9001 – 00033203

The scope of this approval is applicable to:
ISO 9001:2015
Design, Development, Production, Marketing and Sales of Sterilisation Packages, Wrapping Materials, Chemical Indicators, Autoclave Tapes, Bowie-Dick Test Packs, Autoclavable Biohazard Bags, Autoclavable Biohazard Bags with Cardboard Inlay (Class I- Other) and Sealing Machines

Paul Graaf

Area Operations Manager, Europe

Issued by: Lloyd's Register Turkey Quality Control Management Services LLC

for and on behalf of: Lloyd's Register Quality Assurance Limited

TECHNICAL DATA SHEET

AUTOCLAVABLE BIOHAZARD BAG

PRODUCT CODE : OT

RELATED STANDARDS : Autoclavable Biohazard Bag meets the requirements of the Council Directive 94/62/EC on Packaging.

INTENDED USE : Autoclavable Biohazard Bags are used for the sterilization of medical wastes before disposal.

OPERATION CONDITIONS : Autoclavable Biohazard Bags are designed for use in steam sterilization methods. The recommended operation temperature is max. 141 °C. Other sterilization conditions should be determined by the end user regarding to material to be sterilized. During sterilization, bag should be left open for an effective sterilization.

PRODUCT SPECIFICATIONS

PROPERTIES	METHOD	UNIT	VALUE	
THICKNESS (one side)	ISO 534	µm	50 ± 5	
TENSILE STRENGTH	ISO 527-3	N/15 mm	MD	min. 12
			CD	min. 11
ELONGATION AT BREAK	ISO 527-3	%	MD	min. 50
			CD	min. 30
TEAR FORCE	ASTM D 1922	mN	min. 700	

PACKAGING : Autoclavable Biohazard Bags are packaged as the listed below.

Product Code	Dimensions	Unit
OT5370	53 cm x 70 cm	200 pcs/box
OT6389	63 cm x 89 cm	120 pcs/box
OT8790	87 cm x 90 cm	100 pcs/box
OT87110	87 cm x 110 cm	100 pcs/box
OT80110	80 cm x 110 cm	100 pcs/box
OT8070	80 cm x 70 cm	100 pcs/box
OT93115	93 cm x 115 cm	100 pcs/box

PMS

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PRODUCTS

Product Categories

H2O2 PLASMA STERILIZATION

STERILIZATION PACKAGING

– Sterilization Reel

– Sterilization Pouch

– Self-Seal Sterilization Pouch

– EtO Sterilization Pouches

AUTOCLAVABLE BIOHAZARD BAGS

PMSSteripack autoclavable biohazard bags are ideal for processing of biohazardous materials which require autoclaving prior disposal. They provide a safe handling and efficient solution for your biohazard waste management.

High integrity plastic bag withstands 141°C (285°F) maximum autoclave temperature and is designed to resist puncture, tears and leaks.

PMSSteripack autoclavable biohazard bags are available in different sizes and all bags are imprinted with the universal biohazard symbol.

All materials comply with international standards and are manufactures under validated production processes.

SKU: OT Category: Sterilization Packaging Tags: packaging, steam