

**Our product reference: 10-3132EU**

## General product description

Microscope Drape-Zeiss MD 46X64"– sterile.

This Microscope Drape has 3pcs film straps, housing & 65mm len.

The product is packed in sealed pouch, inner box and outer carton.

## General Quality Requirements

Product in compliance with the essential requirements of the Medical Device Directive 93/42/EC As amended by 2007/47/EC, (CE mark) and in conformity with the applicable technical Harmonized standards:

### a) Packaging system (only for product delivered sterile)

Primary packaging for sterile products according to requirements of ISO11607-1:2006.

### b) Sterilization requirements (only for product delivered sterile)

Sterilization guaranteed for a SAL of  $10^{-6}$  when a validated sterilization process is used and

The integrity of primary package during the shelf life of product is assured.

For this purpose the following standards apply:

ISO11135 -1:2007 for Ethylene Oxide method

### c) Biocompatibility requirements

Product is physiologically compatible when used according to its intended purpose.

Based on supplier's information, all materials and components to be in contact with patient or Medical staff are non toxic and do not lead to any sensitization or irritation effects.

### d) Product requirements

Product's general requirements are compliance with EN 13795-1:2002.

## Certification & Approval

**Doc. Date:** 2013-02-01

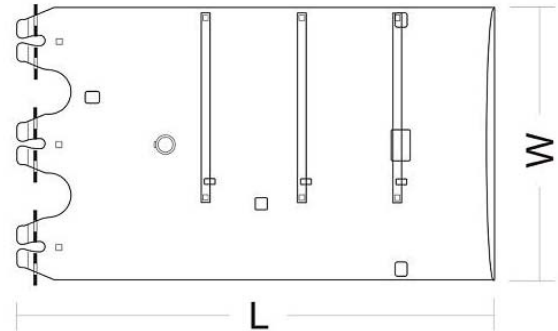
**Distribution:** 2 originals, one for Premier Guard and one for Customer

**Premier Guard** \_\_\_\_\_ *Name:* aaron.xia *Date:* \_\_\_\_\_  
*Office:* Quality Manager

**Customer** \_\_\_\_\_ *Name:* \_\_\_\_\_ *Date:* \_\_\_\_\_  
*Office:* \_\_\_\_\_

## Technical specification

### 1) Dimensions of the product



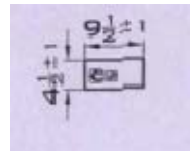
Our Reference:	Size
10-3132EU	46X64" "

### 2) Material description

Base material: 45micron clear PE film

Other relevant material: 3M DS Tape ,hook &loop,3pcs film straps, housing &65mm len

### 3) Folding specification



Folding dimensions: 9.5x4.5"

Tolerances:

Folding: +/-1"

### 4) Packaging specification

Packaging: Seal Pouch+ 12\*8\*9 " inner box + 17\*12.5\*9.5 "carton

Units per box:

Reference:	Units per Box	Units per carton
10-3132EU	10	20