

Our product reference: 10-2103EU

General product description

C-Arm Drape 41x90" – sterile.

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) Packaing system (only for product delivered sterile)

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

b) Sterilisation requirements (only for product delivered sterile)

Sterilisation 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 cytotoxic 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: 2013-10-28

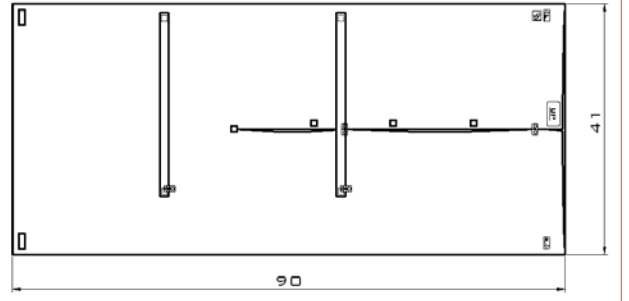
Distribution: 2 originals, one for Premier Guard and one for Customer

Premier Guard _____ *Name:* jimmy *Date:* _____
Office: Quality Manager

Customer _____ *Name:* _____ *Date:* _____
Office: _____

Technical specification

1) Dimensions of the product



Our Reference:	Size
10-2103 EU	41x90"

2) Material description

Base material: 45micron clear PE film

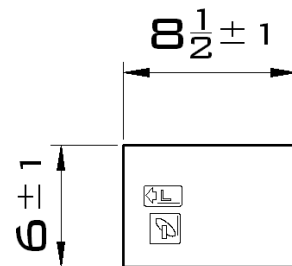
Other relevant material: white PE film, D.S. tape, labels

3) Folding specification

Folding dimensions: 6x8.5"

Tolerances:

Folding: +/-1" (2.5cm)



4) Packaging specification

Packaging: inner box 16*12.*7.5" +17*12.5*15.5" carton

Units per box:

Reference:	Units per box	Units per carton
10-2103EU	20	40