

Our product reference: 13-1742EU

General product description

Cover arm rest 35X73cm -sterile.

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: 2013-05-22

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

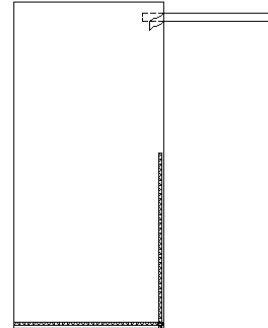
Premier Guard _____ *Name:* Jimmy *Date:* _____
Office: Quality Manager

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

Technical specification

1) Dimensions of the product

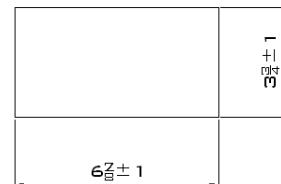
Our Reference:	Size
13-1742EU	35X73cm



2) Material description

Base material: 28g Viscose+25g Film+3g Glue

3) Folding specification



Folding dimensions: 3.75" x6.88"

Tolerances:

Folding: +/-1"

4) Packaging specification

Packaging: carton 15*10*10"

Units per box:

Reference:	Units per carton
13-1742EU	50