

Our product reference: 10-2182EU

General product description

C-ARM KIT–sterile

The product is packed in 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:

ISO11135:2014 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 nontoxic 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: 2018-03-28

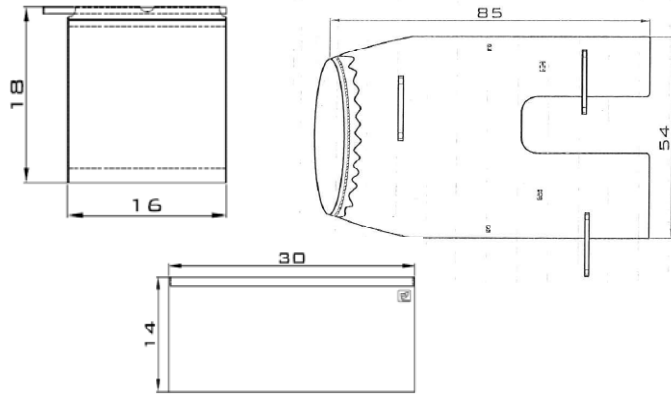
Distribution: 2 originals, one for Premier Guard and one for Customer

Premier Guard _____ *Name:* Arthur Rao *Date:* 20180328
Office: Quality Manager

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

Technical specification

1) Dimensions of the product



Our Reference:	Size
10-2182EU	C-ARM KIT 10-2113 C-ARM DRAPE-MINI 54X85" 1EA 10-8104 FOOT SWITCH COVER W/ BLUE STRAP 16*18*3" 1EA 10-8132 KEYBOARD COVER WITH ADHESIVE 14X30" 1EA

2) Material description

Base material: 41micron clear PE film and 45micron clear PE film, 50micron foggy TPU film

Other relevant material: rubber band and blue PE film, 3pcs film strap, tape

3) Folding specification



Folding dimensions: 6.5"x10"

Tolerances:

Folding: +/-1"

4) Packaging specification

Packaging: Seal Pouch+15.5*12*10"inner box +25*16*10.5"carton

Units per box:

Reference:	Units per Box	Units per carton
10-2182EU	10	20