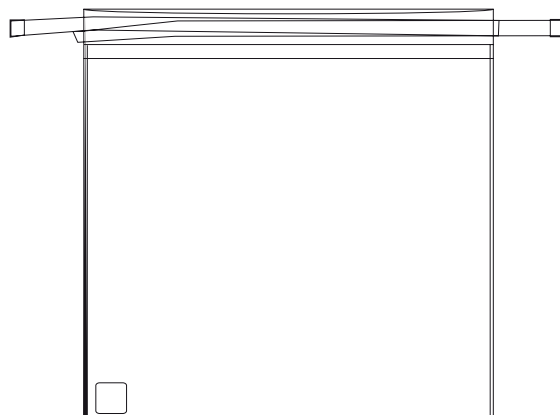




PRODUCT DATASHEET

**ISOLATION BAGS**

REF 10-6161EU

Product Info

Isolation bag with tie closure for storage and isolation in a sterile environment of organs and body parts during surgery. Produced in accordance with legal regulations for medical devices. EO sterilized according to the latest updated version of 11135-1: 2007 standard.

Product name	REF	Size	Pack count
Isolation bag	10-6161EU	51 x 51 cm	10/20

Technical Summary

Regulations:	The product covered by this data sheet does not contain substances classified as carcinogenic, mutagenic or toxic for reproduction (CMR), including any of the Substances of Very High Concern (SVHC) as listed in the latest available version of the Candidate List published by European Chemicals Agency (ECHA)
Product standards:	Medical Devices Directive 93/42/EEC, Class Is
Quality requirements:	Produced in accordance with ISO 9001 and ISO 13485
Label information:	In accordance with EN ISO 15223-1, EN 980 and EN 1041
Main material:	TPU film, transparent.
Warnings:	Produkten är avsedd för engångsbruk. Vid återanvändning kan produktens egenskaper försämrats och utgöra en patientrisk
Storage recommendation:	Recommended storage in clean, dry space in ambient temperature. Products should be protected from direct sunlight and other intensive light sources
Disposal recommendation:	Follow local instructions
Shelf Life:	5 years