

FOMED INDUSTRIES INC

Directive 93/42/EEC

on medical devices, Annex V

Issue 3

Detailed scope

Annex V Sterility aspects only – Restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions:

Sterile Medical Devices used in General Surgical Procedures including
Sterile gauze swabs (without X-ray), Sterile gauze balls (without X-ray),
Sterile cotton filled sponges, Sterile tracheotomy sponges,
Sterile drain gauze swabs, Sterile drain non-woven swabs, Sterile fluff
gauze rolls, Sterile surgical towels, Sterile non-woven swabs,
Sterile non-woven balls, Sterile dental cotton rolls, Sterile cotton balls,
Sterile cotton tipped applicators, Sterile conforming bandages,
Sterile gauze bandages, Sterile absorbent dressing pads (ABD pads),
Sterile tongue depressors, Sterile dressing sets

Annex V:

Sterile Medical Devices used in General Surgical Procedures including
Sterile gauze swabs with X-ray detectable thread, Sterile gauze balls
with X-ray detectable thread, Sterile lap sponges

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.