

Certificate CN13/20594, continued

## FOMED INDUSTRIES INC ISO 13485:2003 EN ISO 13485:2012

Issue 3

Detailed scope

Manufacture of sterile and non sterile medical dressings including gauze swabs (with/without X-ray), gauze balls (with/without X-ray), lap sponges (washed and unwashed), tracheotomy sponges, drain gauze swabs, surgical towels, non-woven swabs, drain non-woven swabs, non-woven balls, non-woven rolls, dental cotton rolls, dental cotton filled sponges, cotton balls, cotton tipped applicators, gauze and cotton tissues, conforming bandages, W.O.W gauze bandages, fluff gauze rolls, absorbent dressing pads (ABD Pads), dressing sets, tongue depressors

Manufacture of medical dressings including gauze rolls (with/without X-ray), absorbent gauzes, throat packs, cotton filled non woven sponge, absorbent cotton wools, cotton bandages, cotton pads, eye pads, gauze and cotton tissues, triangular bandages, elastic bandages, gauze combine pads, island dressing pads, non adherent pads, transparent pads, stockinettes

Manufacture of medical packing materials including sterilization pouches & reels, Tyvek pouches & reels, SMMS non woven wraps, CSR crepe wraps, indicator Tapes & Labels, paper to paper pouches, paper to film pouches, film to film pouches, non woven pouches, crepe paper pouches, coated paper rolls, transparent composite film rolls,

PE laminated paper rolls

Storage and distribution of disposable non sterile dental instruments including bite trays, impression trays, fluoride foam trays, saliva ejectors, mixing tips, oral tips, surgical tips, evacuation tips, microbrushes, dental hand instruments, patient bibs, brush applicators, sterile-soakers, patient bibs clips, apron boxes, cotton roll dispensers, barrier films, mixing bowls, mixing spatulas, impression injectors

Storage and distribution of disposable non sterile protective products including face masks (Earloop, Tie-on and Moulded cone), bouffant caps, shoe covers, surgical gowns, isolation gowns, protective clothes, isolated clothes, drapes, latex examination gloves, nitrile examination gloves, latex surgical gloves

Providing ETO sterilization service for single use medical device according to ISO11135-1:2007



