EC Certificate Production Quality Assurance System: Certificate CN13/20595

The management system of

FOMED INDUSTRIES INC

No. 20, Hansha Road, Hou hu District, Qianjiang City,
Hubei Province, 433115, P.R. China

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

The scope of registration appears on page 2 of this certificate

This certificate is valid from 25 October 2016 until 24 October 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 24 October 2019
Issue 3. Certified since 18 November 2013

Certification is based on reports numbered CN/WUH 5076

Authorised by

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REPUBLICA MOLDOVA, MUN. CHIȘINĂU, S.R.L. «SOLISANO PRIM», IDNO 1005600003425, SOCIETATEA CU RĂSPUNDERE LIMITATĂ

Digitally signed by Latiș Olga
Date: 2018.12.20 11:53:56 EET
Reason: MoldSign Signature
Location: Moldova

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.