



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

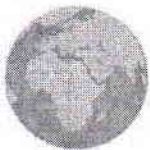
Authorised by

SGS United Kingdom Ltd, Notified Body 0120

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK  
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

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## 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.