EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 01760**

Issued To: **Ranfac Corporation**
30 Doherty Avenue
Avon
Massachusetts
02322
USA

In respect of:

Manufacture and final inspection of sterile suture graspers and sterile bone marrow biopsy needles.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Albert Roossien, Regulatory Lead

First Issued: **1998-01-22** Date: **2019-02-07** Expiry Date: **2023-01-21**

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Supplementary Information to CE 01760

Issued To:

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30 Doherty Avenue
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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 0106	Ranfac® Suture Grasper	Single use, surgically invasive device intended for laparoscopic Suturing
MD 0102	Ranfac® Bone Marrow Aspiration Needle	Single use, surgically invasive device intended for Bone Marrow Biopsy
MD 0102	Ranfac® Marrow Cellution™ Aspiration Needle	Single use, surgically invasive device intended for Bone Marrow Biopsy
MD 0102	Snarecoil® Bone Marrow Biopsy Needle	Single use, surgically invasive device intended for Bone Marrow Biopsy

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Date:	**2019-02-07**
Issued To:	**Ranfac Corporation** **30 Doherty Avenue** **Avon** **Massachusetts** **02322** **USA**

Subcontractor:	**Service(s) supplied**
Emergo Europe Prinsessegracht 20 2514 AP The Hague The Netherlands	**EU Representative**
Professional Contract Sterilization, Inc 40 Myles Standish Boulevard Taunton Massachusetts 02780-1026 USA	**ETO Sterilization**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 01760**

Date: **2019-02-07**

Issued To: **Ranfac Corporation**
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Date	Reference Number	Action
22 January 1998		First Issue
24 May 2001		Ethide Laboratories replaced Microtest Laboratories as Microbiological testing subcontractor
30 July 2003		Deleted manometers and syringes from Scope PCS replaced Cosmed as ETO sterilization subcontractor Certificate renewal
12 February 2004		Addition of Suture Graspers to Scope
25 January 2008	7145588	Certificate renewal and changes to certificate format
30 January 2013	7946622	Addition of EU representatives Novamedisan Italia S.r.l. and Mermaid Medical A/S. Removal of significant subcontractor Ethide Laboratories, Inc. Certificate renewal

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Date	Reference Number	Action
31 October 2017	8861361	Withdrawal of cholangiography catheters, biopsy, suturing and hypodermic needles, breast Care Systems, oral care products, and laparoscopic surgery devices from the certificate scope. Removal of EU Representatives Novamedisan Italia S.r.l. and Mermaid Medical A/S. Addition of EU Representative EMERGO EUROPE. Certificate renewal.
05 September 2018	8959913	Extension to scope to include sterile bone marrow biopsy needles. Administrative update to the certificate format.
Current	7781204	Traceable to NB 0086.