



DET NORSKE VERITAS

PRODUCTION QUALITY MANAGEMENT CERTIFICATE - EC

Certificate No. 46365-2009-CE-USA-NA Rev. 1.0
This Certificate consists of 3 pages

This is to certify that the Quality Management System of

Spectrum Laboratories, Inc. Operating Room Disposables

Irving, USA

for production and final product inspection/testing of

Sterile Drapes, Bandages and Specialty Soft Goods

has been assessed with respect to

the conformity assessment procedure described in Article 11.5 and Annex V (Module D1)
of Council Directive 93/42/EEC on Medical Devices, as amended, for the aspects of manufacture concerned with
securing and maintaining sterile conditions, and found to comply

Further details are given overleaf

Place and date:

Høvik, 04 February 2009

This Certificate is valid until:

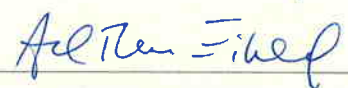
05 February 2014

For DET NORSKE VERITAS CERTIFICATION AS
Norway



CE
Notified Body No.:
0434


Marianne Spæren
Certification Manager


Aud Løken Eiklid
Technical Reviewer

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.

If any person suffers loss or damage which is proved to have been caused by any negligent act or omission of Det Norske Veritas, then Det Norske Veritas shall pay compensation to such person for his proved direct loss or damage. However, the compensation shall not exceed an amount equal to ten times the fee charged for the service in question, provided that the maximum compensation shall never exceed USD 300 000. In this provision "Det Norske Veritas" shall mean the Foundation Det Norske Veritas as well as all its subsidiaries, directors, officers, employees, agents and any other acting on behalf of Det Norske Veritas.



Cert. No.: 46365-2009-CE-USA-NA
Rev. No.: 1.0
Project No.: PRJC-I10636-2008-PRC-USA

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift for Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history

Revision	Description	Issue Date
	Original certificate - first issued	2004-02-05
1.0	Recertification	2009-02-05

Products covered by this Certificate

Product Description	Product Name	Class
Tear Tip Camera Covers	▪ 706931, 706932	I sterile
Mobile & Mini Mobile X-ray Image Intensifier Drapes	▪ 706924, 706925	I sterile
Universal Camera Drapes	▪ 706920, 706921	I sterile
Universal Gamma Probe Covers	▪ 781986	I sterile
Compression Bandages	▪ Esmarch Bandage w/CRS 713309, 713312, 713409, 713412, 713609, 713612 ▪ Esmarch Bandage 714309, 714312, 714409, 714412, 714609, 714612	I sterile
Shoulder Access Positioner	▪ 956944AMS	I sterile

The complete list of devices is filed with the Notified Body.

Sites covered by this certificate

3400 Royalty Row, Irving TX 75062, USA

EU Representative

Spectrum B.V., Breda, Netherlands



Cert. No.: 46365-2009-CE-USA-NA
Rev. No.: 1.0
Project No.: PRJC-110636-2008-PRC-USA

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the local DNV Office of any intended updating of the quality system and DNV will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system DNV reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of DNV.

END OF CERTIFICATE