



DET NORSKE VERITAS

FULL PRODUCT QUALITY MANAGEMENT CERTIFICATE - EC

Certificate No. 16292-2007-CE-NOR Rev. 1.0

This Certificate consists of 3 pages

This is to certify that the Quality Management System of

Ribbel International Ltd.

**Plot No. 10 & 11, Sector 6B, SIDCUL, Integrated Industrial Estate Ranipur, Haridwar - 249 403,
Uttarakhand, India**

for production and final product inspection/testing of

Sterile Disposable Medical Devices

has been assessed with respect to

the conformity assessment procedure described in Article 11.3.a and Annex II exclusive section 4
(Module H) of Council Directive 93/42/EEC on Medical Devices, as amended,
and found to comply

Further details are given overleaf

Place and date:

Høvik, 02 January 2008

This Certificate is valid until:

02 January 2013

For DET NORSKE VERITAS CERTIFICATION AS
Norway

Steinar Kristensen
Certification Manager

Notified Body No.:
0434

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.



DNV

Cert. No.: 16292-2007-CE-NOR
Rev. No.: 1.0
Project No.: PRJC-05970-2007-PRC-IND

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 Social Affairs.

Certificate history

Revision	Description	Issue Date
1.0	Original Certificate	2008-01-02

Products covered by this Certificate

Product Description	Product	Category
Sterile Intravenous Infusion Sets	"RILMED" Brand Type: With or without Air Vent, Microdrip	Class IIa
Sterile Intravenous Cannula	"RILFLON" Brand Size: 12G, 13G, 14G, 16G, 17G, 18G, 20G, 22G, 24G, 26G	Class IIa
Sterile Disposable Single Use Syringes with or without needle	"RILSHOT" Brand Size: 1 ml, 2 ml, 3 ml, 5 ml, 10 ml, 20ml, 50 ml	Class IIa
Sterile Hypodermic Single Use Needles	"RILSHOT" Brand Size: 18G, 20G, 21G, 22G, 23G, 24G, 25G, 26G, 27G	Class IIa

The complete list of the devices is filed with the Notified Body, ref.: PRJC-05970-2007-PRC-IND

Sites covered by this certificate:

Plot No. 10 & 11, Sector 6B, SIDCUL, Ranipur Integrated Industrial Estate, Haridwar – 249 403, Uttarakhand, India