



DET NORSKE VERITAS

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 85552-2010-CE-CZS-NA

This Certificate consists of 3 pages

This is to certify that the Quality Management System of

Dina - Hitex, spol. s r.o.

Ždánská 987, 685 01 Bučovice, Czech Republic

for design, 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 excluding 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, 26 October 2010

This Certificate is valid until:

26 October 2015

For DET NORSKE VERITAS CERTIFICATION AS
NORWAY



Aud Løken Eiklid
Certification Manager

Notified Body No.:
0434

Mariann Jeremiassen
Technical Reviewer

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

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.: 85552-2010-CE-CZS-NA
 Rev. No.:
 Project No.: PRJ-84469-2008-PRC-CZE

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 (2006-OSL-MDD-0373)	2006-09-20
	Recertification	2010-10-26

Products covered by this Certificate:

Product Description	Product	Class
Sterile Disposable Medical Devices	Hitex Composition: drapes, covers, collection bag, sheets, covers, adhesive tapes, incision films, towels, compresses, swabs, bandages, adhesive plasters, bowls, surgical instruments (sponge forceps, scissors, needle holders), vaginal dilators, accessories for use in the operating room (skin markers, tip cleaners, light handle covers, needle safety counting box), accessories of obstetric or newborn treatment set - cotton sheet, rescue blanket, cotton tip applicators	Is
	Hitex Composition: drapes, covers, collection bag, sheets, covers, adhesive tapes, incision films, towels, compresses, swabs, bandages, adhesive plasters, bowls, surgical instruments (sponge forceps, scissors, needle holders), vaginal dilators, accessories for use in the operating room (skin markers, tip cleaners, light handle covers, needle safety counting box), accessories of obstetric or newborn treatment set - cotton sheet, rescue blanket, cotton tip applicators, abdominal drapes, syringes, needles, umbilical clamps, scalpels, gloves, catheters, I.V. infusion sets with accessories (extension line, manifold)	IIa
	Hitex Composition: drapes, covers, collection bag, sheets, covers, adhesive tapes, incision films, towels, compresses, swabs, bandages, adhesive plasters, bowls, surgical instruments (sponge forceps, scissors, needle holders), vaginal dilators, accessories for use in the operating room (skin markers, tip cleaners, light handle covers, needle safety counting box), accessories of obstetric or newborn treatment set - cotton sheet, rescue blanket, cotton tip applicators, abdominal drapes, syringes, needles, umbilical clamps, scalpels, gloves, catheters, I.V. infusion sets with accessories (extension line, manifold), transfusion sets, tubing and connectors, drainage systems with accessories – foams, surgical sutures – non absorbable	IIb



Cert. No.: 85552-2010-CE-CZS-NA
Rev. No.:
Project No.: PRJ-84469-2008-PRC-CZE

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

Sites covered by this certificate

Site Name	Address
Dina - Hitex, spol. s r.o.	Ždánská 987, 685 01 Bučovice, Czech Republic

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