

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

In accordance with the requirements of the Medical Devices
Directive 93/42/EEC and the Medical Devices Regulations 2002, UK
Statutory Instrument 2002 No. 618

This is to certify that the Quality Management System of:

Chemi-Pharm AS
Tänassilma tee 11,
Tänassilma kula,
Saku vald Harju maakond
76406

has been assessed against the requirements of Annex II of the Medical Devices Directive 93/42/EEC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No:

LRQ 4001506/C

Original Approval:

25 May 2004

Current Certificate:

8 April 2019

Certificate Expiry:

7 July 2019

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited



EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM CERTIFICATE LRQ 4001506/C SCHEDULE

In accordance with the requirements of the Medical Devices
Directive 93/42/EEC and the Medical Devices Regulations 2002, UK
Statutory Instrument 2002 No. 618
Chemi-Pharm AS
Tänassilma tee 11,
Tänassilma kula,
Saku vald Harju maakond
76406

Class IIb Products

Disinfectants for invasive medical devices: CHEMIHYD DES

STERISEPT

STERISEPT – Ready to Use CHEMIDES PULVER

Class IIa Products

Disinfectants for non-invasive medical devices:

BACTICID

BACTICID WIPES

DES INSURANCE

ALKADENT

ACIDENT

CLEAN FOAM

WHITEWASH DES MD

CHEMISEPT WIPES MD

CHEMISEPT MD

CHLORINEX - 60 MD

SMELL NET MD

STERIDENT

CHEMIPHARM DES NEW MD

CHEMISEPT HF

STERISEPT FORTE

STERISEPT WIPES

BACTICID AF

Schedule Issue:

01

Date of Schedule Issue:

8 April 2019

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited

1 Trinity Park, Bickenhill Lane, Birmingham B37 7ES, United Kingdom.