

QUALITY SYSTEM

EC-CERTIFICATE

Directive 93/42/EEC

Manufacturer: Chemi-Pharm AS
Tänassilma tee 11
Tänassilma, Saku vald,
Harju maakond 76406
Estonia

Coverage of Certificate: Design, manufacture and final inspection

Product category: Disinfectants for medical
instruments and medical surfaces

Valid until: 27 May 2024

The manufacturer's quality system for the design, manufacture and final inspection of the aforesaid product category has been evaluated and meets the provisions of Council Directive 93/42/EEC as set out in Annex II Section 3. This approval is valid until the expiry date provided that the manufacturer fulfils the obligations imposed by Annex II in Directive 93/42/EEC. Products covered by the certificate are specified in the attachment(s).

Valid from: 11 September 2019

Certificate no.
C-01-1215-699-19



Notified Body no. 0537:
Eurofins Expert Services
Kivimiehentie 4
FI-02150 ESPOO, FINLAND

Attachment 1 to the Certificate number: C-01-1215-699-19

Manufacturer:	Chemi-Pharm AS Tänassilma tee 11, Tänassilma, Saku vald, Harju maakond 76406 Estonia		
Activity and product category:	Design, manufacture and final inspection of disinfectants for medical instruments and medical surfaces. GMDN-code(s): 47631, 58077		
Products:	The certificate covers the following products:		
	<i>Name</i>	<i>Brand name</i>	<i>Class</i>
	Disinfectant for invasive medical instruments	CHEMIHYD DES	IIb
	Disinfectant for invasive medical instruments	STERISEPT	IIb
	Disinfectant for invasive medical instruments	STERISEPT – Ready to Use	IIb
	Disinfectant for invasive medical instruments	STERISEPT INSTRU	IIb
	Disinfectant for invasive medical instruments	STERISEPT WIPES	IIb
	Disinfectant for invasive medical instruments	CHEMIDES PULVER	IIb
	Disinfectant for non-invasive medical surfaces	BACTICID	IIa
	Disinfectant for non-invasive medical surfaces	BACTICID WIPES	IIa
	Disinfectant for non-invasive medical instruments	DES INSURANCE	IIa
	Disinfectant for non-invasive medical instruments	ALKADENT	IIa
	Disinfectant for non-invasive medical instruments	ACIDENT	IIa
	Disinfectant for non-invasive medical surfaces	CLEAN FOAM	IIa
	Disinfectant for non-invasive medical surfaces	WHITEWASH DES MD	IIa
	Disinfectant for non-invasive medical surfaces	CHEMISEPT WIPES MD	IIa



Eurofins Expert Services is Notified Body no. 0537 under Council Directive 93/42/EEC.

EUROFINS EXPERT SERVICES

Medical Devices
Kivimiehentie 4
FI-02150 ESPOO, FINLAND

Business ID FI22975132

Attachment 1 to the Certificate number: C-01-1215-699-19

<i>Name</i>	<i>Brand name</i>	<i>Class</i>
Disinfectant for non-invasive medical surfaces	CHEMISEPT MD	IIa
Disinfectant for non-invasive medical surfaces	SMELL NET MD	IIa
Disinfectant for non-invasive medical surfaces	STERIDENT	IIa
Disinfectant for non-invasive medical surfaces	CHEMIPHARM DES New MD	IIa
Disinfectant for non-invasive medical surfaces	CHEMISEPT HF	IIa
Disinfectant for non-invasive medical surfaces	STERISEPT FORTE	IIa
Disinfectant for non-invasive medical surfaces	BACTICID AF	IIa
Disinfectant for non-invasive medical surfaces	STERISEPT PLUS	IIa
Disinfectant for non-invasive medical surfaces	BACTICID AF WIPES	IIa
Date:	Valid from: 20 December 2019	
		

This attachment 1 supersedes the previous attachment 1 signed 11 September 2019.

Eurofins Expert Services is Notified Body no. 0537 under Council Directive 93/42/EEC.

EUROFINS EXPERT SERVICES

Medical Devices
 Kivimiehentie 4
 FI-02150 ESPOO, FINLAND

Business ID FI22975132

KOKYBĖS SISTEMA

EB SERTIFIKATAS

Direktyva 93/42/EEB

Gamintojas:	Chemi-Pharm AS Tänassilma tee 11 Tänassilma, Saku vald, Harju maakond 76406 Estija
Sertifikato taikymo sritis:	Projektavimas, gamyba ir galutinė patikra
Produktų kategorija:	Dezinfekantai medicininiam instrumentams ir medicininiam paviršiams
Galioja iki:	2024 m. gegužės 27 d.

Anksčiau nurodytos kategorijos produktų projektavimui, gamybai ir galutinei patikrai taikoma gamintojo kokybės sistema buvo įvertinta ir atitinka Tarybos direktyvos 93/42/EEB nuostatas, nustatytas II priedo 3 dalyje. Šis patvirtinimas galioja iki galiojimo pabaigos datos, su sąlyga, kad gamintojas vykdys įsipareigojimus, nustatytus pagal 93/42/EEB direktyvos II priedą. Produktai, kuriems taikomas šis sertifikatas, yra nurodyti priede (-uose).

Galioja nuo: 2019 m. rugsėjo 11 d.

/Parašas/



Sertifikato Nr.
C-01-1215-699-19

/Antspaudas:
Eurofins Expert
Services OY/

/Parašas/



Notifikuotosios įstaigos Nr. 0537:
Eurofins Expert Services
Kivimiehentie 4
FI-02150 ESPOO, SUOMIJA

Priedas Nr. 1 prie sertifikato Nr.: C-01-1215-699-19

Gamintojas:	Chemi-Pharm AS Tänassilma tee 11, Tänassilma, Saku vald, Harju maakond 76406 Estija		
Veikla ir produkto kategorija:	Dezinfekantų medicininiam instrumentams ir medicininiam paviršiams projektavimas, gamyba ir galutinė patikra GMDN kodas (-ai): 47631, 58077		
Produktai:	Sertifikatas taikomas šiems produktams:		
	<i>Pavadinimas</i>	<i>Prekės ženklas</i>	<i>Klasė</i>
	Dezinfekantas invaziniams medicininiam instrumentams	CHEMIHYD DES	IIb
	Dezinfekantas invaziniams medicininiam instrumentams	STERISEPT	IIb
	Dezinfekantas invaziniams medicininiam instrumentams	STERISEPT – Ready to Use	IIb
	Dezinfekantas invaziniams medicininiam instrumentams	STERISEPT INSTRU	IIb
	Dezinfekantas invaziniams medicininiam instrumentams	CHEMIDES PULVER	IIb
	Dezinfekantas invaziniams medicininiam instrumentams	STERISEPT WIPES	IIb
	Dezinfekantas neinvaziniams medicininiam paviršiams	BACTICID	IIa
	Dezinfekantas neinvaziniams medicininiam paviršiams	BACTICID WIPES	IIa
	Dezinfekantas neinvaziniams medicininiam paviršiams	CHEMIDES PULVER	IIa
	Dezinfekantas neinvaziniams medicininiam instrumentams	DES INSURANCE	IIa
	Dezinfekantas neinvaziniams medicininiam instrumentams	ALKADENT	IIa
	Dezinfekantas neinvaziniams medicininiam instrumentams	ACIDENT	IIa
	Dezinfekantas neinvaziniams medicininiam paviršiams	CLEAN FOAM	IIa
	Dezinfekantas neinvaziniams medicininiam paviršiams	WHITEWASH DES MD	IIa
	Dezinfekantas neinvaziniams medicininiam paviršiams	CHEMISEPT WIPES MD	IIa

„Eurofins Expert Services“ yra notifikuotoji įstaiga Nr. 0537 pagal Tarybos direktyvą 93/42/EEB.

Kivimiehentie 4
FI-02150 ESPOO, SUOMIJA

v. 1.1 / 10.9.2018

/Logotipas: Eurofins
Expert Services/

2 (2)

/Logotipas: FINAS
Finnish Accreditation Service
S021 (EN ISO/IEC 17021-1)/

Priedas Nr. 1 prie sertifikato Nr.: C-01-1215-699-19

<i>Pavadinimas</i>	<i>Prekės ženklas</i>	<i>Klasė</i>
Dezinfekantas neinvaziniams mediciniams paviršiams	CHEMISEPT MD	IIa
Dezinfekantas neinvaziniams mediciniams paviršiams	SMELL NET MD	IIa
Dezinfekantas neinvaziniams mediciniams paviršiams	STERIDENT	IIa
Dezinfekantas neinvaziniams mediciniams paviršiams	CHEMIPHARM DES New MD	IIa
Dezinfekantas neinvaziniams mediciniams paviršiams	CHEMISEPT HF	IIa
Dezinfekantas neinvaziniams mediciniams paviršiams	STERISEPT FORTE	IIa
Dezinfekantas neinvaziniams mediciniams paviršiams	BACTICID AF	IIa
Dezinfekantas neinvaziniams mediciniams paviršiams	STERISEPT PLUS	IIa
Dezinfekantas neinvaziniams mediciniams paviršiams	BACTICID AF WIPES	IIa
Data:	Galioja nuo 2019 m. rugsėjo 11 d.	
	<i>/Antspaudas:</i> Eurofins Expert Services OY/	
<i>/Parašas/</i>		<i>/Parašas/</i>

„Eurofins Expert Services“ yra notifikuotoji įstaiga Nr. 0537 pagal Tarybos direktyvą 93/42/EEB.

EUROFINS EXPERT SERVICES

Medical Devices

Kivimiehentie 4

FI-02150 ESPOO, SUOMIJA

Verslo ident. kodas FI22975132

v. 1.1 / 10.9.2018