

## QUALITY SYSTEM

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# EC-CERTIFICATE

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## 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

  
Riina Uusmies

  
Olli Kakkonen

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**

<b>Manufacturer:</b>	Chemi-Pharm AS Tänassilma tee 11, Tänassilma, Saku vald, Harju maakond 76406 Estonia		
<b>Activity and product category:</b>	Design, manufacture and final inspection of disinfectants for medical instruments and medical surfaces. GMDN-code(s): 47631, 58077		
<b>Products:</b>	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 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
	Disinfectant for non-invasive medical surfaces	CHEMISEPT 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	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
<b>Date:</b>	Valid from: 11 September 2019		
	 Riina Uusmies	  Olli Kakkonen	

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## 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/*

Riina Uusmies

Sertifikato Nr.

**C-01-1215-699-19**

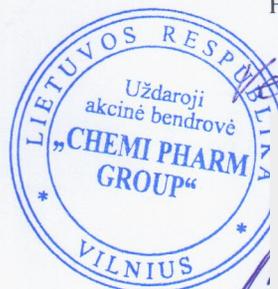
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Eurofins Expert  
Services OY/

*/Parašas/*

Olli Kakkonen

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



/Logotipas: Eurofins  
Expert Services/

1 (2)

/Logotipas: FINAS  
Finnish Accreditation Service  
S021 (EN ISO/IEC 17021-1)/**Priedas Nr. 1 prie sertifikato Nr.: C-01-1215-699-19**

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

/Antspaudas:  
Eurofins Expert  
Services OY/

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

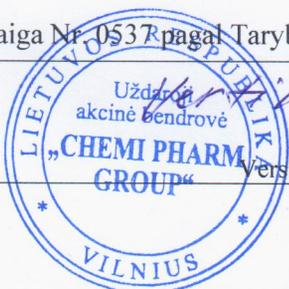
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FI-02150 ESPOO, SUOMIJA

v. 1.1 / 10.9.2018



Vertimas iš anglų kalbos

11

/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 medicininiam paviršiams	SMELL NET MD	Ila
	Dezinfekantas neinvaziniams medicininiam paviršiams	STERIDENT	Ila
	Dezinfekantas neinvaziniams medicininiam paviršiams	CHEMIPHARM DES New MD	Ila
	Dezinfekantas neinvaziniams medicininiam paviršiams	CHEMISEPT HF	Ila
	Dezinfekantas neinvaziniams medicininiam paviršiams	STERISEPT FORTE	Ila
	Dezinfekantas neinvaziniams medicininiam paviršiams	BACTICID AF	Ila
	Dezinfekantas neinvaziniams medicininiam paviršiams	STERISEPT PLUS	Ila
	Dezinfekantas neinvaziniams medicininiam paviršiams	BACTICID AF WIPES	Ila
<b>Data:</b>	Galioja nuo 2019 m. rugsėjo 11 d.		
	<i>/Parašas/</i> Riina Uusmies	<i>/Antspaudas:</i> Eurofins Expert Services OY/	<i>/Parašas/</i> Olli Kakkonen

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*Antspaudas*