

## 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

  
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Riina Uusmies

  
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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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**EUROFINS EXPERT SERVICES**

Medical Devices

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v. 1.1 / 10.9.2018

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