

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


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

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 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
Date:	Valid from: 11 September 2019		
			
	 Riina Uusmies	 Olli Kakkonen	

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