

QUALITY SYSTEM

EC-CERTIFICATE

Directive 93/42/EEC

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

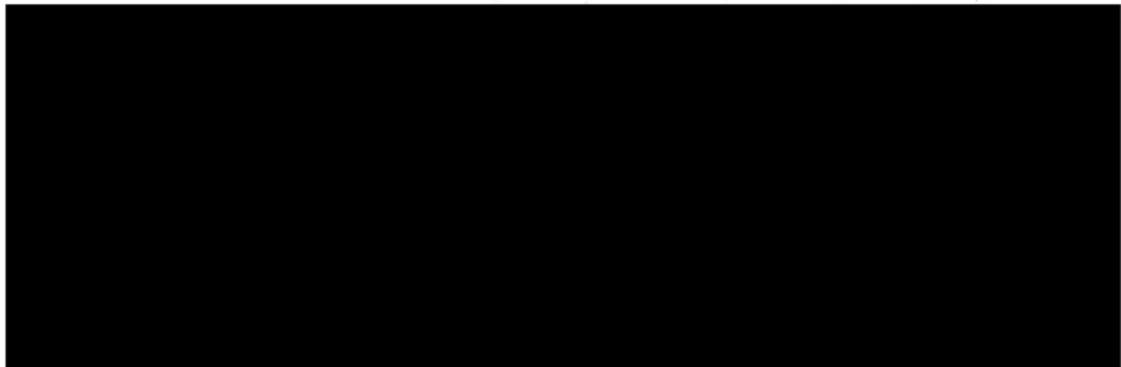
Coverage of Certificate: Design, manufacture and final inspection

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



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

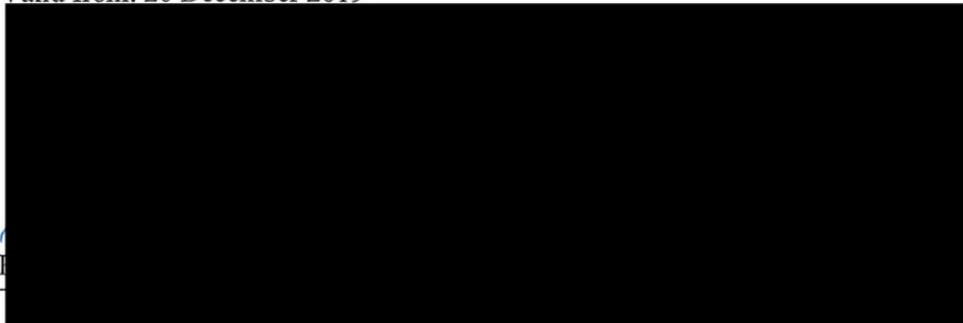
Business ID FI22975132

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
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Business ID FI22975132

v. 1.1 / 10.9.2018

KOKYBĖS SISTEMA

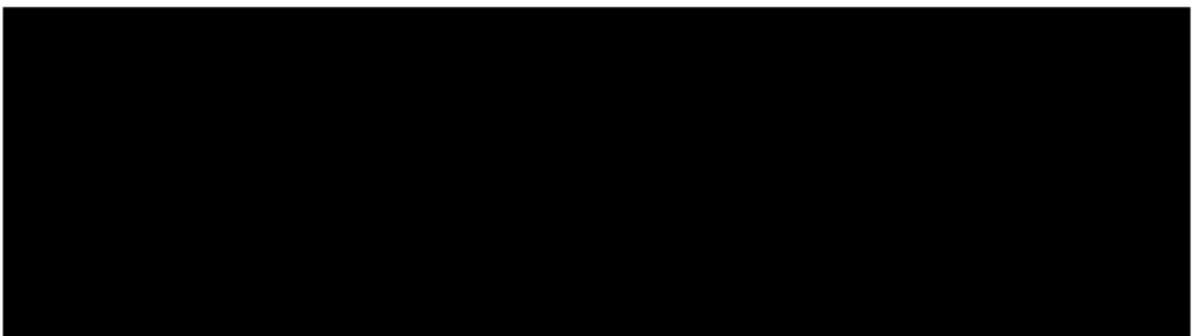
EB SERTIFIKATAS

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.



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

/Antspaudas:
Eurofins Expert
Services OY/

„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/

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/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	Ila
Dezinfekantas neinvaziniams mediciniams paviršiams	SMELL NET MD	Ila
Dezinfekantas neinvaziniams mediciniams paviršiams	STERIDENT	Ila
Dezinfekantas neinvaziniams mediciniams paviršiams	CHEMIPHARM DES New MD	Ila
Dezinfekantas neinvaziniams mediciniams paviršiams	CHEMISEPT HF	Ila
Dezinfekantas neinvaziniams mediciniams paviršiams	STERISEPT FORTE	Ila
Dezinfekantas neinvaziniams mediciniams paviršiams	BACTICID AF	Ila
Dezinfekantas neinvaziniams mediciniams paviršiams	STERISEPT PLUS	Ila
Dezinfekantas neinvaziniams mediciniams paviršiams	BACTICID AF WIPES	Ila

Data:

Galioja nuo 2019 m. rugsėjo 11 d.

/Antspaudas:
Eurofins Expert

„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
v. 1.1 / 10.9.2018

Verslo ident. kodas FI22975132

Notified body confirmation letter

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **Eurofins Electric & Electronics Finland Oy**, a notified body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the **number 0537** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Chemi-Pharm AS
Tänassilma road 11
76406 Tänassilma village, Harju county
ESTONIA
SRN Number: EE-MF-000001521

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. **Table 1** identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. **Table 2** identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as reusable surgical instruments)

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

<i>Device name under MDR application</i>	<i>MDR device classification (as proposed by the manufacturer and verified at the pre-application stage)</i>	<i>If the MDR device is a substitute device, identification of the corresponding MDD device</i>	<i>MDD certificate reference of the devices under MDR application, and the NB identification</i>
CHEMIHYD DES	Class IIb excluding class IIb implantable non-WET	N/A, same device.	C-01-1215-699-19 / Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)
STERISEPT	Class IIb excluding class IIb implantable non-WET	N/A, same device.	C-01-1215-699-19 / Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)
STERISEPT – Ready to Use	Class IIb excluding class IIb implantable non-WET	N/A, same device.	C-01-1215-699-19 / Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)
STERISEPT INSTRU	Class IIb excluding class IIb implantable non-WET	N/A, same device.	C-01-1215-699-19 / Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)
STERISEPT WIPES	Class IIb excluding class IIb implantable non-WET	N/A, same device.	C-01-1215-699-19 / Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)
CHEMIDES PULVER	Class IIb excluding class IIb implantable non-WET	N/A, same device.	C-01-1215-699-19 / Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)
BACTICID	Class IIa	N/A, same device.	C-01-1215-699-19 / Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)
BACTICID WIPES	Class IIa	N/A, same device.	C-01-1215-699-19 / Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)
DES INSURANCE	Class IIa	N/A, same device.	C-01-1215-699-19 / Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)

ALKADENT	Class IIa	N/A, same device.	C-01-1215-699-19 / Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)
ACIDENT	Class IIa	N/A, same device.	C-01-1215-699-19 / Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)
CLEAN FOAM	Class IIa	N/A, same device.	C-01-1215-699-19 / Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)
WHITEWASH DES MD	Class IIa	N/A, same device.	C-01-1215-699-19 / Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)
CHEMISEPT WIPES MD	Class IIa	N/A, same device.	C-01-1215-699-19 / Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)
CHEMISEPT MD	Class IIa	N/A, same device.	C-01-1215-699-19 / Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)
SMELL NET MD	Class IIa	N/A, same device.	C-01-1215-699-19 / Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)
STERIDENT	Class IIa	N/A, same device.	C-01-1215-699-19 / Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)
CHEMIPHARM DES New MD	Class IIa	N/A, same device.	C-01-1215-699-19 / Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)
CHEMISEPT HF	Class IIa		C-01-1215-699-19 / Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)

STERISEPT FORTE	Class IIa	N/A, same device.	C-01-1215-699-19 / Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)
BACTICID AF	Class IIa	N/A, same device.	C-01-1215-699-19 / Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)
STERISEPT PLUS	Class IIa	N/A, same device.	C-01-1215-699-19 / Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)
BACTICID AF WIPES	Class IIa	N/A, same device.	C-01-1215-699-19 / Eurofins Electric & Electronics Finland Oy (at the time, Eurofins Expert Services)

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive

<i>Device name under MDR application</i>	<i>MDR device classification (as proposed by the manufacturer and verified at the pre-application stage)</i>	<i>If the MDR device is a substitute device, identification of the corresponding MDD device</i>	<i>MDD certificate reference of the devices under MDR application, and the NB identification</i> Or <i>N/A – MDD class I device</i>
N/A	N/A	-	-

Confirmation Letter Revision History

Revision	Date	NB internal reference traceable to each version of the letter	Description of changes
1.0	20.05.2024	Letter no. 1 THTR-02-L08 (NB-1215; 24.10.2022) THTR-02-L08 (NB-1215; 20.05.2024) C-01-1215-699-19, Attachment 1	Initial version

Notifikuotosios įstaigos patvirtinimo laiškas

Visiems suinteresuotiesiems,

oficialios paraiškų statuso patvirtinimas, rašytinis susitarimas ir tinkamos stebėsenos vykdymas pagal Reglamentą ES 2023/607, kuriuo iš dalies keičiami reglamentai (ES) 2017/745 ir (ES) 2017/746 dėl pereinamojo laikotarpio nuostatų, taikomų konkrečioms medicinos prietaisams ir in vitro diagnostikos medicinos prietaisams.

Šiuo laišku patvirtinama, kad „Eurofins Electric & Electronics Finland Oy“, notifikuotoji įstaiga (NB), paskirta pagal Reglamentą (ES) 2017/745 (MDR) ir pažymėta NANDO numeriu **0537**, pagal MDR VII priedo 4.3 skirsnio pirmąją pastraipą gavo oficialią paraišką ir pagal MDR VII priedo 4.3 skirsnio antrąją pastraipą pasirašė rašytinį susitarimą su toliau nurodytu gamintoju:

„Chemi-Pharm AS“
Tanassilma road 11
76406 Tanassilma village, Harju county
ESTONIA (Estija)
SRN numeris: EE-MF-000001521

Prietaisai, kuriems taikoma pirmiau minėta oficiali paraiška ir rašytinis susitarimas, išvardyti toliau pateiktose lentelėse. **1 lentelėje** nurodomi prietaisai, dėl kurių gauta MDR paraiška, sudarytas rašytinis susitarimas ir dėl kurių NB taip pat yra atsakinga už atitinkamų prietaisų stebėsenos vykdymą (pagal taikomą direktyvą). **2 lentelėje** nurodomi prietaisai, dėl kurių gauta MDR paraiška ir sudarytas rašytinis susitarimas, tačiau dėl kurių NB dar nepriėmė jokios atsakomybės už atitinkamų prietaisų stebėsenos vykdymą (pagal taikomą direktyvą).

Prietaisų, kuriems taikomi pagal Direktyvą 93/42/EEB (MDD) išduoti sertifikatai, kurių galiojimas baigėsi po 2021 m. gegužės 26 d. ir iki 2023 m. kovo 20 d. ir kurie nebuvo panaikinti, atveju šiuo laišku taip pat patvirtinama, kad gamintojas pasirašė rašytinį susitarimą pagal MDR iki MDD sertifikato galiojimo pabaigos dienos; arba pateikė įrodymų, kad valstybės narės kompetentinga institucija iki 2023 m. kovo 20 d. atitinkamiems prietaisams taikė nukrypti leidžiančią nuostatą arba išimtį nuo taikytinos atitikties vertinimo procedūros pagal atitinkamai MDR 59 straipsnio 1 dalį arba MDR 97 straipsnio 1 dalį.

Toliau pateikiami pereinamojo laikotarpio terminai, taikomi šiame laiške nurodytiems prietaisams, jei gamintojas ir toliau laikosi kitų MDR 120.3c straipsnyje (su pakeitimais, padarytais (ES) 2023/607) nurodytų sąlygų:

- 2026 m. gegužės 26 d. – III klasės specialiai sukurti implantuojami prietaisai;
- 2027 m. gruodžio 31 d. – III klasės prietaisai ir IIb klasės implantuojami prietaisai, išskyrus gerai žinomas technologijas (WET – siūlai, sąvaržos, plombos, breketai, vainikėliai, sraigtai, pleištai, plokštelės, vielos, smeigės, sąvaržos ir sujungimo priemonės);
- 2028 m. gruodžio 31 d. – kiti IIb klasės prietaisai, IIa klasės prietaisai, I klasės prietaisai, pateikti rinkai steriliomis sąlygomis arba atliekantys matavimo funkciją;
- 2028 m. gruodžio 31 d. – prietaisai, kuriems pagal MDD nereikia notifikuotosios įstaigos patvirtinimo, tačiau pagal MDR jis būtinas (pvz., I klasės prietaisai, kurie laikomi daugkartinio naudojimo chirurginiais instrumentais).

1 lentelė. Prietaisai, kuriems taikomas šis laiškas ir dėl kurių NB taip pat yra atsakinga už atitinkamų prietaisų stebėsenos vykdymą pagal taikomą direktyvą:			
<i>Prietaiso pavadinimas pagal MDR paraišką</i>	<i>MDR prietaiso klasifikacija (kaip pasiūlyta gamintojo ir patikrinta prieš pateikiant paraišką)</i>	<i>Jei MDR prietaisas yra pakaitinis prietaisas, atitinkamo MDD prietaiso identifikavimas</i>	<i>Prietaisų, kuriems taikoma MDR paraiška, MDD sertifikato nuoroda ir NB identifikacija</i>
CHEMIHYD DES	IIB klasė, išskyrus IIB klasės implantuojamus ne WET prietaisus	Netaikoma, tas pats prietaisas	C-01-1215-699-19/ „Eurofins Electric & Electronics Finland Oy“ (tuo metu – „Eurofins Expert Services“)
STERISEPT	IIB klasė, išskyrus IIB klasės implantuojamus ne WET prietaisus	Netaikoma, tas pats prietaisas	C-01-1215-699-19/ „Eurofins Electric & Electronics Finland Oy“ (tuo metu – „Eurofins Expert Services“)
STERISEPT – paruošta naudoti	IIB klasė, išskyrus IIB klasės implantuojamus ne WET prietaisus	Netaikoma, tas pats prietaisas	C-01-1215-699-19/ „Eurofins Electric & Electronics Finland Oy“ (tuo metu – „Eurofins Expert Services“)
STERISEPT INSTRU	IIB klasė, išskyrus IIB klasės implantuojamus ne WET prietaisus	Netaikoma, tas pats prietaisas	C-01-1215-699-19/ „Eurofins Electric & Electronics Finland Oy“ (tuo metu – „Eurofins Expert Services“)
STERISEPT WIPES	IIB klasė, išskyrus IIB klasės implantuojamus ne WET prietaisus	Netaikoma, tas pats prietaisas	C-01-1215-699-19/ „Eurofins Electric & Electronics Finland Oy“ (tuo metu – „Eurofins Expert Services“)
CHEMIDES PULVER	IIB klasė, išskyrus IIB klasės implantuojamus ne WET prietaisus	Netaikoma, tas pats prietaisas	C-01-1215-699-19/ „Eurofins Electric & Electronics Finland Oy“ (tuo metu – „Eurofins Expert Services“)
BACTICID	IIA klasė	Netaikoma, tas pats prietaisas	C-01-1215-699-19/ „Eurofins Electric & Electronics Finland Oy“ (tuo metu – „Eurofins Expert Services“)
BACTICID WIPES	IIA klasė	Netaikoma, tas pats prietaisas	C-01-1215-699-19/ „Eurofins Electric & Electronics Finland Oy“ (tuo metu – „Eurofins Expert Services“)
DES INSURANCE	IIA klasė	Netaikoma, tas pats prietaisas	C-01-1215-699-19/ „Eurofins Electric & Electronics Finland Oy“ (tuo metu – „Eurofins Expert Services“)

ALKADENT	Ila klasė	Netaikoma, tas pats prietaisas	C-01-1215-699-19 / „Eurofins Electric & Electronics Finland Oy“ (tuo metu – „Eurofins Expert Services“)
ACIDENT	Ila klasė	Netaikoma, tas pats prietaisas	C-01-1215-699-19/ „Eurofins Electric & Electronics Finland Oy“ (tuo metu – „Eurofins Expert Services“)
CLEAN FOAM	Ila klasė	Netaikoma, tas pats prietaisas	C-01-1215-699-19/ „Eurofins Electric & Electronics Finland Oy“ (tuo metu – „Eurofins Expert Services“)
WHITEWASH DES MD	Ila klasė	Netaikoma, tas pats prietaisas	C-01-1215-699-19/ „Eurofins Electric & Electronics Finland Oy“ (tuo metu – „Eurofins Expert Services“)
CHEMISEPT WIPES MD	Ila klasė	Netaikoma, tas pats prietaisas	C-01-1215-699-19/ „Eurofins Electric & Electronics Finland Oy“ (tuo metu – „Eurofins Expert Services“)
CHEMISEPT MD	Ila klasė	Netaikoma, tas pats prietaisas	C-01-1215-699-19/ „Eurofins Electric & Electronics Finland Oy“ (tuo metu – „Eurofins Expert Services“)
SMELL NET MD	Ila klasė	Netaikoma, tas pats prietaisas	C-01-1215-699-19/ „Eurofins Electric & Electronics Finland Oy“ (tuo metu – „Eurofins Expert Services“)
STERIDENT	Ila klasė	Netaikoma, tas pats prietaisas	C-01-1215-699-19/ „Eurofins Electric & Electronics Finland Oy“ (tuo metu – „Eurofins Expert Services“)
CHEMIPHARM DES New MD	Ila klasė	Netaikoma, tas pats prietaisas	C-01-1215-699-19/ „Eurofins Electric & Electronics Finland Oy“ (tuo metu – „Eurofins Expert Services“)
CHEMISEPT HF	Ila klasė	Netaikoma, tas pats prietaisas	C-01-1215-699-19/ „Eurofins Electric & Electronics Finland Oy“ (tuo metu – „Eurofins Expert Services“)

STERISEPT FORTE	Ila klasė	Netaikoma, tas pats prietaisas	C-01-1215-699-19 / „Eurofins Electric & Electronics Finland Oy“ (tuo metu – „Eurofins Expert Services“)
BACTICID AF	Ila klasė	Netaikoma, tas pats prietaisas	C-01-1215-699-19/ „Eurofins Electric & Electronics Finland Oy“ (tuo metu – „Eurofins Expert Services“)
STERISEPT PLUS	Ila klasė	Netaikoma, tas pats prietaisas	C-01-1215-699-19/ „Eurofins Electric & Electronics Finland Oy“ (tuo metu – „Eurofins Expert Services“)
BACTICID AF WIPES	Ila klasė	Netaikoma, tas pats prietaisas	C-01-1215-699-19/ „Eurofins Electric & Electronics Finland Oy“ (tuo metu – „Eurofins Expert Services“)

2 lentelė. Prietaisai, kuriems taikomas šis laiškas, tačiau dėl kurių NB NĖRA atsakinga už atitinkamų prietaisų stebėsenos vykdymą pagal taikomą direktyvą

<i>Prietaiso pavadinimas pagal MDR paraišką</i>	<i>MDR prietaiso klasifikacija (kaip pasiūlyta gamintojo ir patikrinta prieš pateikiant paraišką)</i>	<i>Jei MDR prietaisas yra pakaitinis prietaisas, atitinkamo MDD prietaiso identifikavimas</i>	<i>Prietaisų, kuriems taikoma MDR paraiška, MDD sertifikato nuoroda ir NB identifikacija</i> Arba <i>Netaikoma – MDD I klasės prietaisas</i>
Netaikoma	Netaikoma	-	-

Patvirtinimo laiško peržiūrų istorija

Peržiūra	Data	NB vidinė nuoroda, atsekama pagal kiekvieną laiško versiją	Pakeitimų aprašymas
1.0	2024-05-20	<u>Laiškas Nr.: 1</u> THTR-02-L08 (NB-1215; 2022-10-24) THTR-02-L08 (NB-1215; 2024-05-20) C-01-1215-699-19, 1 priedas	Pradinė versija

