

QUALITY SYSTEM

EC-CERTIFICATE

Directive 93/42/EEC

Manufacturer: Galena Pharma Oy
Sammonkatu 10
FI-70500 Kuopio
Finland


Coverage of Certificate: Design, manufacture and final inspection

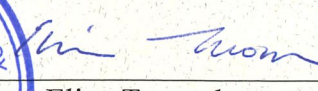
Product category: Gastrointestinal gas suppressants
Skin moisture barrier dressings
Wound cleaning solutions
Ear care products
Stool softeners
Lactic acid based products for vaginal mucosa protection
Ointments for damaged skin
Oils for dry and irritated vaginal mucosa

Valid until: 7th March, 2023

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: 24th May, 2021


Aliisa Siljander


Elina Tuomola

Certificate no.
C-01-1162-775-21

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



Attachment 1 to the Certificate number: C-01-1162-775-21

Manufacturer:	Galena Pharma Oy Sammonkatu 10, FI-70500 Kuopio, Finland			
Activity and product category:	Design, manufacture and final inspection Gastrointestinal gas suppressants; GMDN 47579 Skin moisture barrier dressings; GMDN 46206 Wound cleaning solutions; GMDN 59523 Ear care products; GMDN 46259, 46206 Stool softeners; GMDN 57795 Lactic acid based products for vaginal mucosa protection; GMDN 47601 Ointments for damaged skin; GMDN 63108 Oils for dry and irritated vaginal mucosa; GMDN 47899			
Products:	The certificate covers the following products:			
	<i>Name</i>	<i>Brand name</i>	<i>Model</i>	<i>Class</i>
	Medical device for alleviation of flatulence	Simex 80 mg	Tablet	IIa
	Medical device for skin care	Xyliderm	Gel	IIa
	Medical device for skin care	Xyliderm+Vitamin D	Gel	IIa
	Ear oil	Otocur	Spray / Drops	IIa
	Stool softener	YA Makrogoli	Powder for oral solution	IIb
	Stool softener	YA Makrogoli suolaton	Powder for oral solution	IIb
	Wound cleaning solution	YA Haavapuhdiste	Spray / Solution	IIa
	Wound cleaning solution	Apteekki Antiseptinen Haavanpuhdiste	Spray / Solution	IIa
	Wound cleaning solution	Wonderm Antisepti	Spray / Solution	IIa
	Lactic acid based product for vaginal mucosa protection	YA Emätingeeli	Gel	IIa
		Femisan Balance	Gel	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-01-1162-775-21

	Ointment for damaged skin	Ceraderm Betaglucan	Ointment	IIa
	Oil for dry and irritated vaginal mucosa	Ceraderm intime	Oil	IIb
Date:	Valid from: 24 th May, 2021			
	<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;">  Aliisa Siljander </div> <div style="text-align: center;">  </div> <div style="text-align: center;">  Elina Tuomola </div> </div>			

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v. 1.1 / 10.9.2018