

## QUALITY SYSTEM

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**EC-CERTIFICATE**

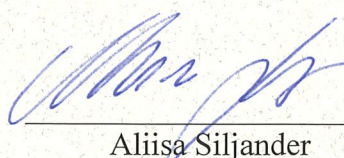
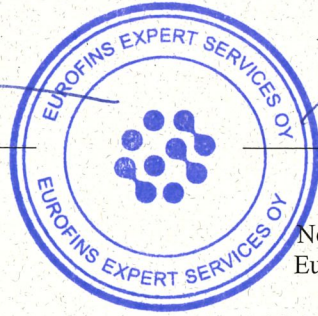
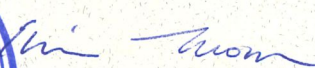
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## Directive 93/42/EEC

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:	7 <sup>th</sup> 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: 24<sup>th</sup> May, 2021

 _____ Aliisa Siljander		 _____ Elina Tuomola
Certificate no. <b>C-01-1162-775-21</b>		Notified Body no. 0537: Eurofins Expert Services Kivimiehentie 4 FI-02150 ESPOO, FINLAND