

MANAGEMENT SYSTEM

CERTIFICATE

Certificate no. C-7093-60-18

ISO 13485:2016

Galena Pharma Oy

Sammonkatu 10, 70500 Kuopio

Eurofins Expert Services Oy has assessed the company's management system and found that it meets the requirements of ISO 13485:2016.

This certificate covers the following functions/services:

Design, manufacture final inspection and sales of medical devices for gastrointestinal and for topical (skin, ear) use.

Issued: 27th November 2018

Valid until: 27^h November 2021

First issued: 6th March 2013

Olli Kakkonen Certifier Eurofins Expert Services Oy

Oll Kale

Mikko Soikkeli Lead Auditor Eurofins Expert Services Oy

S021 (EN ISO/IEC 17021-1)