

QUALITY MANAGEMENT SYSTEM

EU-CERTIFICATE

Regulation (EU) 2017/745

Manufacturer: Galena Pharma Oy
Sammonkatu 10
70500 Kuopio
Finland

Single registration number: FI-MF-000000588

Conformity assessment procedure: Regulation (EU) 2017/745 Annex IX

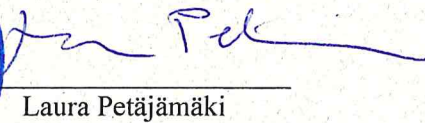
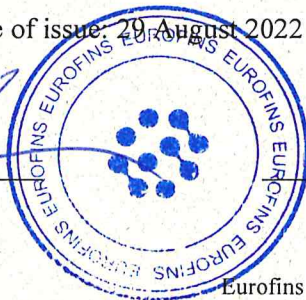
Device category: MDN 1213 Non-active non-implantable devices composed of substances to be introduced into the human body via a body orifice or the dermal route

Date of expiry: 30 June 2027

The manufacturer's quality management system covering the device category has been assessed and approved in accordance with the Annex IX to Regulation (EU) 2017/745. Approval shall be valid until the expiry date provided that the manufacturer fulfills the obligations imposed by Annex IX in Regulation. The products covered by the certificate and the details related to the maintenance of this certificate are specified in the attachment to the certificate.

Date of issue: 29 August 2022



Aliisa Siljander

Laura PetäjämäkiCertificate no:
CR-03-1162-806-22Notified Body no. 0537:
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Information about the examinations and tests as per MDR Annex XII, section 10,
is available upon request from EES-medical@eurofins.fi.