eurofins

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 Petäjämäki

Certificate no:

CR-03-1162-806-22

Notified 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.