

CUSTOMER NOTIFICATION – LORNE LABORATORIES POSITION ON UKCA MARKING

Date: 17 SEP 2026

Subject: UKCA Marking of Lorne Laboratories IVD Products

To: Valued Customers,

Dear Customer,

Lorne Laboratories continuously monitors applicable regulatory requirements to ensure ongoing compliance of all products supplied to our customers.

Following a review of current UK medical device regulations, Lorne Laboratories has taken the decision to defer implementation of UKCA marking for applicable In Vitro Diagnostic (IVD) products at this time.

Under current UK regulatory provisions, CE-marked IVD products may continue to be placed on the Great Britain market until **30 June 2030**, in accordance with the applicable transition arrangements. Therefore, Lorne Laboratories will continue to supply CE-marked products in compliance with current regulatory requirements.

Reference:

MHRA, *Regulating medical devices in the UK*, GOV.UK, last updated 20 February 2026.

Available at: <https://www.gov.uk/guidance/regulating-medical-devices-in-the-uk#ce-marking-and-notified-bodies>

This decision does not impact:

- Product quality, safety or performance.
- Product availability.
- Regulatory compliance of products currently supplied by Lorne Laboratories.
- Customer use of Lorne products.

Lorne Laboratories will continue to monitor regulatory developments and will implement any required changes in accordance with applicable regulatory timelines.

Should you require any further information or clarification, please do not hesitate to contact us.

Sincerely,



Digitally signed by
Visweswara Sharma Pokkuluri
Date: 2026.09.24 10:57:57
+01'00'

Name: Visweswara Sharma Pokkuluri
Role: Lead Regulatory Affairs Coordinator
Lorne Laboratories

Molecular Dimensions Ltd t/a Lorne Laboratories
Unit 1 Cutbush Park Industrial Estate
Danehill, Lower Earley
Berkshire RG6 4UT United Kingdom
Tel: +44 (0) 118 921 2264
Email: info@lornelabs.com
www.lornelabs.com