

# Gibco sera will be discontinuing the CE mark and IVD on its labels

## FAQs

### Why are we removing the CE/IVD mark from all Gibco™ sera labels?

Since most of our customers use Gibco sera in “further manufacturing processes” or for research purposes, we’re aligning our product labeling to reflect this use. The CE-marked and **For In Vitro Diagnostic (IVD)** products will continue to be supplied until current inventories have been depleted. In late 2017, you will start to receive sera products without the CE mark and the IVD statement on the label and other associated documentation. The new product use statement that will appear on Gibco sera labeling and associated documentation will be: **For Research Use or Further Manufacturing Use only. Serum and blood proteins are not for direct administration into humans or animals.**

This label change will not affect the product composition or quality standards that we have in place today. All serum products will continue to be manufactured under our current global quality management systems.

### What if I currently use sera in a regulated product or process?

Depending on how your regulated product or process is documented, you may need to amend your specifications and/or registrations. If necessary, please communicate directly with your local competent authority for guidance on what updates are required. Should you need any assistance, please contact [techsupport@thermofisher.com](mailto:techsupport@thermofisher.com)

### Will European Directorate for the Quality of Medicines (EDQM) Certificates of Suitability remain valid now that the CE marking is no longer on Gibco sera labels?

Yes. Our existing EDQM Certificates of Suitability were issued based on Transmissible Spongiform Encephalopathies (TSE) risk mitigation, relative to the strict sourcing and processing of our sera products and are not associated with the CE marking and *in vitro* diagnostic usage currently applied to them. These same certificates remain valid even with the CE mark removed and the usage statement change.

Find out more at [thermofisher.com/gibcolabelchanges](http://thermofisher.com/gibcolabelchanges)

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**For Research Use or Further Manufacturing. Not for diagnostic use or direct administration into humans or animals.**

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