Quality Certificate

VWR® LAB MARKERS

As per the manufacturer, the below given product meets the following criteria:

North American Catalog No:	52877-355
Lot Number:	230160
Description:	VWR Lab Marker Fine Blue PK10
Date of Manufacture:	July 2020

The product was manufactured in accordance with the current FDA Quality System Regulation 21 CFR Part 820, Medical Device Directive 93/42/EEC, Medical Device Quality Management System EN ISO 13485, and Canadian Medical Device Regulation SOR/98-282.

Quality Control Testing:

Representative production samples are collected and inspected in accordance with current applicable product specifications. Inspection records are reviewed and signed off by qualified personnel for product release.

Device Listing/Manufacturing Site Registration/Pre-market Notification:

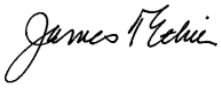
Medical Devices are listed with FDA per 21CFR 807. Manufacturing sites are registered with FDA per 21CFR 807. The devices satisfy FDA pre-market notification requirements per 21 CFR 807.

Sterilization:

All products which are labeled as sterile and released for sale.They are certified to be sterile as long as the package is unopened and undamaged. Sterilization cycle development / validation has been performed in accordance with current ANSI/AAMI/ISO guidelines.

- Product sterilized using Gamma Radiation was sterilized in compliance with EN ISO 11137 (Radiation Sterilization Requirements for Development, Validation and Routine Control).
- Product sterilized using Ethylene Oxide was sterilized in compliance with EN ISO 11135 (Ethylene Oxide Sterilization Requirements for Development, Validation and Routine Control).

Signed:



Jamie Ethier
VP Global Quality
VWR, Part of Avantor

Date: October 14, 2020