

# **Bản tiêu chuẩn Chủ sở hữu công bố áp dụng**

*Tài liệu được xác nhận bằng chữ ký số*

*Hà Nội, ngày 23 tháng 11 năm 2022*

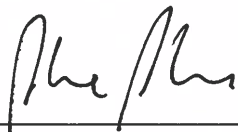
**Người đại diện hợp pháp của cơ sở**

**GIÁM ĐỐC**

**Uông Tuấn Phương**

**Release Test Specifications**Product Name: **LIAISON Insulin****REF: 310360**

Activity	Specification
Checking the correctness of calibration and operating parameters reported in the labels	<p><b>1- In order for the LIAISON® BarCode label of the lot under test to be approved:</b></p> <ol style="list-style-type: none"> <li>1. The specific and functional lot parameters described, such as lot number, expiry date, doses assigned to the calibrators and permitted limits of oscillation for signal and dose, reference Master Curve ID, product code, number of assays and integral layout must be as defined when determining the parameters (calibrator approval);</li> <li>2. The BarCode test label must be correctly recognized on the LIAISON® analyzer.</li> </ol> <p><b>2- In order for the LIAISON® XL RFTag of the lot under test to be approved:</b></p> <ol style="list-style-type: none"> <li>1. The specific lot parameters described, such as lot number, expiry date, doses assigned to the calibrators, permitted limits of oscillation for signal and dose, reference Master Curve parameters and Geometric Curve Check parameters must be as defined when determining the parameters (calibrator approval);</li> <li>2. The functional parameters described, such as article number, layout, number of assays and calibrations, available volumes and LLD values, must be as defined for the product in question (data of previous lot or description of reference RFTag);</li> <li>3. The test RFTag must be correctly recognized on the LIAISON® XL analyzer.</li> </ol>
Functional check after packaging in customer mode	<p>The decision regarding the conformity of the release test for the lot under test is taken on the basis of the fulfillment of the acceptance criteria set down in the product specification for the control phase in question in the DiaBLO LabWare®LIMS QC test management software.</p> <p>Requirements on the test management SW of CQ DiaBLO LabWare®LIMS: the calibration must be validable and controls must be within label limits.</p>

*Authorised Signatory:*

**Dr. Andrea Armando**

Corporate Director

Regulatory Affairs Operations &amp; China