

# E-Track Application (BCIL)

# Kusum Healthcare

Operational Qualification Document

This user's guide includes the operational qualification protocols defined for the application.

Prepared By: Omkar Gaonkar

Version Number: 1.0.0

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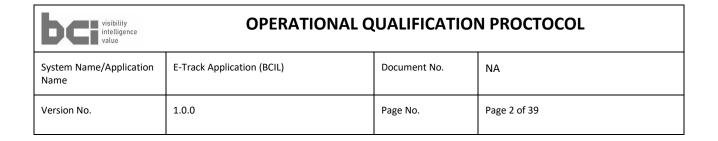
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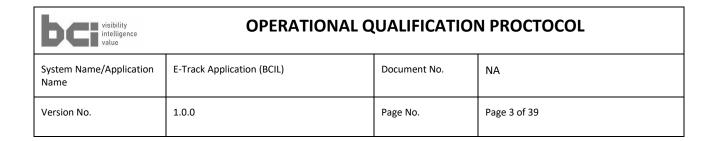
#### **REVISION HISTORY**

Revision Number	Date	Prepared By	Reviewed By	Comment
1.0.0	21-Nov-2022	Omkar G	Chandrakant S	New Release



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## 1 PROTOCOL APPROVAL

## **By BCI Team**

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# **By Kusum Team**

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Department	Nar	me	Designation	Signature & Date		

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#### 2 OBJECTIVE

The objective of this document is to provide written procedure and/or guidelines and respective acceptance criteria for the Operation Qualification of E-Track Application (BCIL) with documented evidence that system is working as per design and will perform & control the process in operating mode, so as to protect the integrity & quality of the system.

#### 3 SCOPE

The scope of this document is limited to outline procedure / provide methodology for the operational qualification of equipment / system within the following boundaries.

- Verification of the Functional Keys, Sequential operation
- Verification of relevant SOPs for their operational accuracy (such as operation, etc).

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# 4 Software OQ

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# 5 WEB APPLICATION

#### 5.1 LOGIN

Test Parameter	Test Procedure	Expected Result	Test (Yes/No)

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#### 5.2 Company Master

Test Parameter	Test Procedure	Expected Result	Test (Yes/No)

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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#### 5.3 Plant Master

Test Parameter	Test Procedure	Expected Result	Test (Yes/No)

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL			
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#### 5.4 USER MASTER

Test Parameter	Test Procedure	Expected Result	Test (Yes/No)

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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#### 5.5 GTIN MASTER

Test Parameter	Test Procedure	Expected Result	Test (Yes/No)

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL			
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#### 5.6 LINE MASTER

Test Parameter	Test Procedure	Expected Result	Test (Yes/No)

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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## 5.7 Consignee Master

Test Parameter	Test Procedure	Expected Result	Test (Yes/No)

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#### 5.8 Printer Master

Test Parameter	Test Procedure	Expected Result	Test (Yes/No)

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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## 5.9 Label Design Master

Test Parameter	Test Procedure	Expected Result	Test (Yes/No)

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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## 5.10 REPORTS

Test Parameter	Test Procedure	Expected Result	Test (Yes/No)

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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#### 5.11 Generation report

Test Parameter	Test Procedure	Expected Result	Test (Yes/No)

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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## 5.12 SECONDARY PRINTING REPORT

Test Procedure	Expected Result	Test (Yes/No)
	Test Procedure	Test Procedure Expected Result

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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#### 5.13 Tertiary Printing Report

Test Parameter	Test Procedure	Expected Result	Test (Yes/No)

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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#### 5.14 OUTWARD REPORT

Test Parameter	Test Procedure	Expected Result	Test (Yes/No)

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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#### 5.15 Mapping Report

Test Parameter	Test Procedure	Expected Result	Test (Yes/No)

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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# 5.16 Secondary Rejection/Sample Report

Test Procedure	Expected Result	Test (Yes/No)
	Test Procedure	Test Procedure Expected Result

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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# 5.17 Tertiary Rejection/Sample Report

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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#### 5.18 SECONDARY UN-UTILIZATION REPORT

Test Parameter	Test Procedure	Expected	Test (Yes/No)
		Result	
			ļ ,

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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#### 5.19 Tertiary Un-utilization Report

Test Parameter	Test Procedure	Expected Result	Test (Yes/No)

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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#### 5.20 Audit Trail Report

Test Parameter	Test Procedure	Expected Result	Test (Yes/No)

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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#### 5.21 BATCH REPORT

Test Parameter	Test Procedure	Expected Result	Test (Yes/No)

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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#### 5.22 CLIENT APPLICATION- LOGIN

Test Parameter	Test Procedure	Expected Result	Test (Yes/No)

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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#### 5.23 BATCH CREATION

Test Parameter	Test Procedure	Expected Result	Test (Yes/No)

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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#### 5.24 SERIAL NO GENERATION

Test Parameter	Test Procedure	Expected Result	Test (Yes/No)

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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#### 5.25 BARCODE PRINTING

Test Parameter	Test Procedure	Expected Result	Test (Yes/No)

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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# 5.26 Rejection of Generation Report

Test Procedure	Expected Result	Test (Yes/No)
	Test Procedure	Test Procedure Expected Result

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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# 5.27 SERIAL NO. REJECTION

Test Procedure	Expected Result	Test (Yes/No)
	Test Procedure	Test Procedure Expected Result

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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# 5.28 Job Creation

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visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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## 5.29 Online Scanning

Test Parameter	Test Procedure	Expected Result	Test (Yes/No)

visibility intelligence value	OPERATIONAL QUALIFICATION PROCTOCOL		
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# 6 DEVIATION REPORT

Deviation if any	Available (Yes/No)	Remarks

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7	7 CONCLUSION	

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# 8 PROTOCOL POST APPROVAL

Checked By				
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Approved By					
Department	Name	Designation	Signature & Date		