



BOOMINGSHING

浙江柏明胜医疗科技有限公司

ZB-QR-32043

MEDICAL

Zhejiang Boomingshing Medical Technology Co.,Ltd.

版本号 01

文件类型Doc Type

质量记录Quality Record

页码 1/1

文件名称Doc Name

批生产记录表Batch production record sheet

产品名称Product Name: Assay Tip/Assay cup tray 批号Lot No: 23003908 P03

序号	记录表单名称	表单编号	使用部门	记录情况	备注
1	生产命令单	ERP打印	制造部	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG <input type="checkbox"/> N/A	N/A
2	领(退)料单	ERP打印	制造部	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG <input type="checkbox"/> N/A	N/A
3	成型作业时报表	ZB-QR-32037	制造部	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG <input type="checkbox"/> N/A	N/A
4	注塑成型条件点检表	ZB-QR-32021	制造部	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG <input type="checkbox"/> N/A	N/A
5	清拉检查表	ZB-QR-32012	制造部	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG <input type="checkbox"/> N/A	N/A
6	产成品入库单	ERP打印	制造部	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG <input type="checkbox"/> N/A	N/A
7	进货检验报告	ZB-QR-12068	质量部	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG <input type="checkbox"/> N/A	N/A
8	标签过程检查记录表	ZB-QR-12078	质量部	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG <input type="checkbox"/> N/A	N/A
9	产品首末件确认单	ZB-QR-12071	质量部	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG <input type="checkbox"/> N/A	N/A
10	过程检查记录表	ZB-QR-12051	质量部	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG <input type="checkbox"/> N/A	N/A
11	首件检查尺寸测量表	ZB-QR-12075	质量部	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG <input type="checkbox"/> N/A	N/A
12	QA抽检表	ZB-QR-13015	质量部	<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG <input type="checkbox"/> N/A	N/A
13	OQC出货检查日报表	ZB-QR-12067	质量部	<input type="checkbox"/> OK <input type="checkbox"/> NG <input type="checkbox"/> N/A	待发货。
14	辐照证明书(若有)	(外发)	资料提供给质量部	<input type="checkbox"/> OK <input type="checkbox"/> NG <input checked="" type="checkbox"/> N/A	
15					
16					

制造部

审核: 邹志坚

质量部

审核: 邹志坚管代或管代授权人
批准:

浙江柏明胜医疗科技有限公司

P02

生产命令单

生产订单号	ZBS0602-231200012	生产机台		模具尺寸	
物料编码	B32500010007	厂内物料名称	Assay-rack plain	制单日期	2023-12-22
生产数量	4824	计量单位	件	版本号	
生产批号		水口/模		模具编号	CH2022085D
计划公式(小时)	9.11	日报夹数量		替代模具编号	
颜色		周期(S)	13.6	物料规格	尺寸: 156.65*157.3*
单重g	93.95	穴数	2.000000	尺寸:	66.7mm
外箱数量	0	内箱数量	0	副产品	
生产说明					

完工产品入库记录

日期	机台	穴数	生产量	A/B班	累计生产量	良品数	A/B班	累计良品数	待返工数	A/B班	累计返工数	T.数	生产欠数	A/B班	可用量
13F0103															

制单: 阚善红 审核: 阚善红
 一联白色(计划) 二联蓝色(存根) 三联黄色(物控) 四联红色(领原料) 五联绿色(领器材)
 ZB-QR-32005
 2023-12-22 09:42:11 00000000000000000000000000000000

浙江柏明胜医疗科技有限公司

生产命令单

PL027

生产订单号	ZBS0602-231200013	生产机台		模具尺寸	
物料编码	B32500010006	厂内物料名称	Assay-cup	制单日期	2023-12-25
生产数量	506520	计量单位	个	版本号	
生产批号		水口/模		模具编号	CH2022086D
计划公式(小量)	10, 11	已报关数量		替代模具编号	
颜色		周期(S)	4.6	物料规格	本色, Φ7.0*26.0
单重g	0.142	穴数	64.000000	副产品	
外箱数量	0	内箱数量	0	生产数量	
生产说明		材料规格	子件	仓库	应领数量 单位 可用量
材料编码	材料名称				
13F0106	Red pull-thread 红色易撕条	宽度: 2mm; 材质: PP	采购	1 卷	
A200010047	PP BORILLED RJ880 MO	透明 TRANSPARENT	采购	75 公斤	

完工产品入库记录

日期	机台	穴数	生产量	A/R班	累计生产量	良品数	A/H班	待返工数	A/R班	累返工数	生产欠数	A/H班	备注

审核:陶美红
制单:陶美红
—拉丝(注塑)
—联蓝色(存根)
—联黄色(物控)
—联绿色(领原料)
—联红色(领包装) ZB-QR-32005

浙江柏明胜医疗科技有限公司

(3)



材料出库单

ZBS0611-231200013

出库日期 2023-12-25

仓库 客供仓
包材仓

部门	制造部	出库类型	领料申请单	业务类型	领料
生产订单号	产品编码	产品	材料编码	材料名称	规格型号
ZBS0602-231200010	B32500010005	Assay-tip	B200010060	PP PRD-ELEC	黑色 BLACK
ZBS0602-231200010	B32500010005	Assay-tip	TP16650	Wasteline	尺寸： E2G (E2G废料盒)
ZBS0602-231200010	B32500010005	Assay-tip	13K0051	E2G (E2G废料盒)	145x114x118 mm, 外白色内 套胶袋
ZBS0602-231200010	B32500010005	Assay-tip	13K0051	Wasteline	尺寸： E2G (E2G废料盒)
合计					145x114x118 mm, 外白色内 套胶袋

制单人 带宇婷

审核人 郑海英 2023.12.25

白联：仓库 红联：PMC 黄联：财务

ZB-QR-32010

72323
2023.12.25

浙江柏明胜医疗科技有限公司



材料出库单

ZBS0611-231200014

出库日期 2023-12-25

仓库 客供仓
包材仓

部门	制造部	出库类型	领料申请单	业务类型	领料
生产订单号	产品编码	产品	材料编码	材料名称	规格型号
ZBS0602-231200013	B32500010006	Assay-cup	A200010047	PP BORIED™ RJ880M0	透明 TRANSPARENT
ZBS0602-231200013	B32500010006	Assay-cup	13F0106	Red pull-thread 螺纹	宽度：2mm；材 料：PP
合计					76
					76

制单人 带宇婷

审核人 郑海英 2023.12.25

白联：仓库 红联：PMC 黄联：财务

ZB-QR-32010

72323
2023.12.25

浙江柏明胜医疗科技有限公司

P03



材料出库单

入库单号 ZRS0611-231200015

出库日期 2023-12-22

仓库 客供仓
包材仓

生产订单号	产品编码	产品	材料编码	材料名称	规格型号	单位	实发数量	应发数量	批号	备注
制造部	出库类型	领料申请单								
ZRS0602-231200012	B32500010007	Assay-rack plain	B200130063	LLIPS ALCOM MID PS 1000 AS1415 WT 1113-05	白色 WHITE	KG	167	167	122448804	
ZDS0602-231200012	B32500010007	Assay-rack plain	I3F0103	滤膜 (32MB600 宽度： 320mm, 厚度： 0.032mm)	KG	5	5	2006797		
合计							472	472		

制单人 章宇婷

审核人

白联：仓库 红联：PMC 黄联：财务

ZB-QR-32010

2023.12.22

深圳市柏明胜医疗器械有限公司

P02



材料出库单

山坪单号 BMS0611-231201089

山坪日期 2023-12-25

仓库 包材仓二

部门 制造-部 出库类型 领料冲销单

业务类型 领料

生产订单号	产品编码	产品	材料编码	材料名称	规格型号	单位	实发数量	应发数量	批号	备注
BMS0606-231200042	B10500010002	E2G	160200213	E2G内袋标签	尺寸：72x51, 5mm 黑色印刷	PCS	821	821	126383	
BMS0606-231200042	B40500010002	E2G	160200244	E2G外箱标签	尺寸：141, +专色印刷	PCS	136	136	126382	
DMS0606-231200042	B40500010002	E2G	13A0204	E2G纸箱	尺寸：585*385*235mm, 外层白色带印刷, BE	PCS	134	134	WJ-203384	
DMS0606-231200042	B10500010002	E2G	13A0204-C01	尺寸：572*372mm, 单坑,	棕色	PCS	268	268	WJ-203368	
RMS0606-231200042	B10500010002	E2G	13A0204-S01	尺寸：371*206mm, 棕色,	单坑	PCS	536	536	WJ-204062	
制单人 草宁婷		审核人		日期:		白城: 仓库	红城: PVC	黄城: 财务	BMS-MC-007C	
合计										

深圳市柏明胜医疗器械有限公司



材料出库单

山坪单号 BMS0611-231201089

山坪日期 2023-12-25

仓库 包材仓二

部门 制造-部 出库类型 领料冲销单

业务类型 领料

生产订单号	产品编码	产品	材料编码	材料名称	规格型号	单位	实发数量	应发数量	批号	备注
BMS0606-231200042	B10500010002	E2G	13A0204-L01	长刀卡	尺寸：572*206mm, 棕色,	PCS	402	102	WJ-204061	
BMS0606-231200042	B40500010002	E2G	13W0013	断机小卡板	尺寸：1200*800*14mm	PCS	12	12	P2310001	
BMS0606-231200042	B10500010002	E2G	13A0006	孔板防滑纸	尺寸：1050*	PCS	11	45	20221208	
BMS0606-231200042	B40500010002	E2G	160100035	E2G封箱胶纸	宽度：50mm,	KG	2	2	230913-01	
BMS0606-231200042	B10500010002	E2G	13A0232	人字压膜	内尺寸：1180*	PCS	10	12	SJ-137933	
BMS0606-231200042	B40500010002	E2G	11611514001	雨刮器子	尺寸：1200*	PCS	10	12	SJ-137181	
BMS0606-231200042	B10500010002	E2G	13A0232-D01	雨刮器子	尺寸：748*100mm	PCS	10	12	SJ-137181	
合计										

制单人 草宁婷

审核人

日期: 仓库 红城: PVC 黄城: 财务

BMS-MC-007C

72 红书
2023.12.25

文件类型
Doc Type质量记录
Quality Record页码
Page

1/1

标签打印申请记录表
Label Print Application Record Form

P03

打印申请 Print application Records	标签打印申请记录表 Label Print Application Record Form					
	客户 Customer	机台 Equipment	申请日期 Application date	开始生产日期 (标签上) DOM on label	模具编号 Mold No.	备注 Remarks
产品名称 Product Name	灭菌袋 Sterilization Bag	订单号 Order No.	WMS-20230310-001 Batch No.)	2023.12.24 到期日期 (标签上) DOE on label	2024.11.30 申请人 (生产班长) Applicant	订单数量 Order quantity 4804 补申请原因 Reason for applying for replenishment
申请数量 application quantity	条形码 Bar code	内袋标签 Inner bag label	说明书 specification	外箱标签 Carton Label	审批人 (主管级及以上) Approval by	
第一次 No.1	V	Q21	N	126	陈书贤 13333333333	✓
第二次(补) No.2						
第三次(补) No.3						
第四次(补) No.4						
第五次(补) No.5						
打印数量 printing quantity	打印日期 printing date	打印人员 printer	外箱标签 Carton Label	内袋标签 Inner bag label	说明书 specification	条形码 Barcode
第一次 No.1	2023.12.29	张敬	126	321	✓	✓
第二次 No.2						
第三次 No.3						
第四次 No.4						
第五次 No.5						
第六次 No.6						
第七次 No.7						
第八次 No.8						
第九次 No.9						
第十次 No.10						
第十一次 No.11						
第十二次 No.12						
第十三次 No.13						
第一次 No.1						
第二次 No.2						
第三次 No.3						
第四次 No.4						

备注:条码、内外箱标签补打时, 需要记录在补打申请栏内, 不使用框用/表示, 字体工整不可随意涂改, 每批次存档保存。
Note: Barcode and inner and outer box labels need to be recorded in the field of application for reprinting, do not use the box /, the font is neat and cannot be altered at will, and each batch is stored in the archive

机号: 2B-1-31 - 0022 生产订单号: 3556002-271200012 批号: S27120006

质量记录Quality Record

成型作业时报表Production Process Hourly Tracking Report

客户 Customer	品名 Part name	平衡平衡 Balance of off-shift	平衡平衡 Balance of on-job shift	待处理数 To be dispose qty	Yield/Hr	产量 Hr Yield/hour
报检数 Inspect quantity	箱CTN (袋Bag) * N/A = 896			N/A	450	450 Pcs.

时 [h]	良品数 Accepted q'ty	类别 Category	外观不良 Cosmetic defects						功能不良 Functional defects	撕裂线不 line tear	包装膜不良 Packing film defects	标签不良 Label defects	判定结果 judgement result:	备注 Remark						
08:00-09:00	180	人选 Manual sorted	0	黑点 black spot	气泡 bubble	划伤 Scratch	缩水 Shrinkage	鼓包穿孔 Bulge/tear	短料 Short	油污 Oil mark	异物 Foreign substance	毛刺/划伤 Burr/flash	不满良率 Unfilled rate	漏印不规 Attendance printing NG	偏移 offset >2mm	被污染 Contaminated	焊接不良 Welding is incomplete	损坏不在位 Not firmly attached	信息不良 Information	其他不良 Others
09:00-10:00	434	人选 Manual sorted	1																OK	NG
10:00-11:00	432	人选 Manual sorted	2																OK	NG
11:00-12:00	430	人选 Manual sorted	0																OK	NG
12:00-13:00	438	机选 Machine sorted	0																OK	NG
13:00-14:00	372	人选 Manual sorted	0																OK	NG
14:00-15:00	432	机选 Machine sorted	0																OK	NG
15:00-16:00	440	人选 Manual sorted	1																OK	NG
16:00-17:00	435	机选 Machine sorted	0																OK	NG
17:00-18:00	345	人选 Manual sorted	0																OK	NG
18:00-19:00	428	机选 Machine sorted	0																OK	NG
19:00-20:00	426	人选 Manual sorted	1																OK	NG
合计: Total			4792	N/A	b														OK	NG

说明:1.本班尾数必须由下一班全部接收;
Note:1.On-duty shifts must take over the balance quantity left by the off duty shifts;

生产特殊活动记录表

Special Case Records during production

时间 Time	问题原因 Causes of the problem	处理方法 Disposing methods	责任认签名 Person signature
08:00-09:00	启动机器, 检查各部件正常运行。	启动 20min to the machine	李继峰
09:00-10:00	Start up debugging, this piece confirmation	Products that have been started up for 20 min directly scrapped.	李继峰
10:00-11:00			
11:00-12:00			
12:00-13:00			
13:00-14:00	模具保养	Clean the mold surface with a dust-free cloth.	李继峰
14:00-15:00	Mold maintenance.	Wipe the mold surface with a clean cloth.	李继峰
15:00-16:00			
16:00-17:00			
17:00-18:00	模具保养	Clean the mold surface with a dust-free cloth.	李继峰
18:00-19:00			
19:00-20:00			

备注: 此表记录非生产外的各项工作, 包括但不限于: 1.上班初期开机、调机、下模 2.自动换模换腔 3. 各种异常处理 4. 常温清机换模 5. 加热/冷却加风机、放大板 6. 各种停机记录 7. 特殊活动记录 8. 正常生产。且非空白部分, 当生产不良率超过警戒值时, 需立即停止生产并进行机台改善。Note: This record is for non-production work, including but not limited to: 1. Startup at the beginning of the shift, adjustment, demolding, mold changing; 2. Automatic line label adjusting and changing; packaging machine adjustment; 3. Abnormal handling; 4. Line improvement (such as adding fan or magnifier); 5. Heating, cooling, change or adding of equipment; 6. Machine abnormal shutdown; 7. Note in normal if no abnormal happens, and mark N/A in blank section. When the production defect rate exceeds 5%, the technician should be notified immediately to stop the improvement.

质量记录Quality Record

成型作业时报表Production Process Hourly Tracking Report

模具编号: C40220707 2023 年 12 月 MM 20 日 DD Shift

Mould No: C40220707 2023 12 MM 20 DD Shift

机号: Line#	生产订单号: Job order#	批号: Lot No.	文件编号Doc No.
报检数 Inspect qty	品名: Part name	周用 Cycle	文件版本号Version
15	箱CTN (袋Bag) × 1 = 1500	上班尾数 Balance of off. shift	下班尾数 Balance of on-job shift
%: 1	客户 Customer	余量 H Yield/H	待处理数 To be dispose qty

时间 Time	良品数 Accepted qty	类别 Category	外观不良 Cosmetic defects	功能不良 Functional defects	撕裂线不 Pack film defects	包装膜不良 Label defects	标签不良	备注 Remark
08:00-09:00	NA	人选 Manual sorted	黑点 black spot	气泡 bubble	划伤/碰伤 Scratch/Impact	缩水 Shrinkage	缺胶穿孔 Oil mark	异物 Foreign
09:00-10:00	31	机选 Machine sorted					油污 Oil mark	毛刺/划伤 Burr/Flash
10:00-11:00	63	人选 Manual sorted					不洁/灰尘 Un-clean	不洁/灰尘 Un-clean
11:00-12:00	64	机选 Machine sorted					喊叫不连贯 Attendant NG	喊叫不连贯 Attendant NG
12:00-13:00	45	人选 Manual sorted					印刷 NG Printing NG	印刷 NG Printing NG
13:00-14:00	65	机选 Machine sorted					损坏/污染 Damage/contamination	损坏/污染 Damage/contamination
14:00-15:00	64	人选 Manual sorted					焊接不良 Welding is incomplete	焊接不良 Welding is incomplete
15:00-16:00	63	机选 Machine sorted					损坏/污染 Damage/contamination	损坏/污染 Damage/contamination
16:00-17:00	64	人选 Manual sorted					损坏/污染 Damage/contamination	损坏/污染 Damage/contamination
17:00-18:00	48	机选 Machine sorted					损坏/污染 Damage/contamination	损坏/污染 Damage/contamination
18:00-19:00	64	人选 Manual sorted					损坏/污染 Damage/contamination	损坏/污染 Damage/contamination
19:00-20:00	64	机选 Machine sorted					损坏/污染 Damage/contamination	损坏/污染 Damage/contamination
合计: Total	625	人选 Manual sorted					损坏/污染 Damage/contamination	损坏/污染 Damage/contamination

说明:1.本班尾数必须由下一班全部接收; Note:1. On-duty shifts must take over the balance quantity left by the off duty shifts;								
生产特殊活动记录表 Special case records during production								
时间 Time	原因原因 Cause of the problem	处理方法 Disposing methods	责任人签名 Person Signature					
08:00-09:00	Start up. 1st piece. first piece confirmation	Product info to 2nd run. Plan to the trial. Product info to 2nd run. Plan to the trial.	NA					
10:00-11:00		Product info to 2nd run. Plan to the trial. Product info to 2nd run. Plan to the trial.	NA					
11:00-12:00		Product info to 2nd run. Plan to the trial. Product info to 2nd run. Plan to the trial.	NA					
12:00-13:00		Product info to 2nd run. Plan to the trial. Product info to 2nd run. Plan to the trial.	NA					
13:00-14:00		Product info to 2nd run. Plan to the trial. Product info to 2nd run. Plan to the trial.	NA					
14:00-15:00		Product info to 2nd run. Plan to the trial. Product info to 2nd run. Plan to the trial.	NA					
15:00-16:00		Product info to 2nd run. Plan to the trial. Product info to 2nd run. Plan to the trial.	NA					
16:00-17:00		Product info to 2nd run. Plan to the trial. Product info to 2nd run. Plan to the trial.	NA					
17:00-18:00		Product info to 2nd run. Plan to the trial. Product info to 2nd run. Plan to the trial.	NA					
18:00-19:00	Mold maintenance	Clean the mold surface with a dust free cloth.	NA					
19:00-20:00		Clean the mold surface with a dust free cloth.	NA					

备注:此表记录正常生产外的各种活动,包括但不限于下面项目: 1.注塑上机开机、调机、下机 2.自动线调整等。 3.各报警处理 4.设备检修执行(比如冲床加料机、放料机) 5.注塑、自动线设备的维修、空里、零件更换等。各种异常情况记录 7.无异常情况备注 正常生产, 并且 N/A(白手部分: 当生产出现异常情况时, 请通知技术员/领班改善。 Note: This report records all activities happened outside normal production, including but not limited to: 1. up-loading mold, machine start, machine adjustment and down-loading mold; 2. Automatic line label adjusting and changing, packaging machine adjustment; 3. Abnormal alarms handling; 4. Line improvement such as adding on fan or magnifier); 5. Repairing, change or adding of equipment; 6. Machine abnormal shutdown; 7. None in normal if no abnormal happens, and mark N/A in blank section. When the production defect rate exceeds 5%, the technician should be notified immediately to stop the improvement.

作业员Operator: 刘富强 2023.12.30 班长Prod leader/技师Technician:

课长QC leader/经理Manager:

尹金龙 2023.12.30

质量记录Quality Record

成型作业时报表Production Process Hourly Tracking Report

模具编号Mould No.

CH2022-86D

CH2022-87D

2023年 12月 30 日 DD Shift

文件类型Doc Type	生产订单号Job order#	批号Lot No.	页数Page
机号: Machine# Line 29	YMS0606-231209P	23001998	1/1

Customer	品名Part name	上机尾数Balance of off-shift	周用Cycle	空缺Cavity	本班尾数Balance of on-job shift	Yield/Hr	待处理数To be dispose qty																
报检数Inspect qty	箱CTN (袋Bag) × 1 = 5PC						65 PCS																
不良品数Defect: 2 PCS																							
不良率Defect rate: 1.2% (目标值Target values%) 判定结果Judgement result: OK □ NG																							
时间Time	良品数Accepted qty	类别Category	外观不良Cosmetic defects	功能不良Functional defects	撕裂线不Tear line	包装膜不良Packing film defects	标签不良Label defects																
20:00-21:00	65	人选 Manual sorted	黑点 Black spot	气泡 Bubble	划伤/碰伤 Scratch/Impact	缩水 Shrinkage	胶接穿孔 Short shoot	油污 Oil mark	异物 Foreign substance	毛刺/划伤 Burr/Flash	不漏气oles Non-leak holes	印刷不良 PrintNG	偏移offset	破损损坏 Damaged	焊接不牢 Welding incomplete	污染损坏 Contamination	粘贴不牢 Not firmly attached	信息不清 Information not clear	Others				
21:00-22:00	65	人选 Manual sorted																	Normal 正常				
22:00-23:00	40	人选 Manual sorted																	正常 Normal				
23:00-24:00		机选 Machine sorted																	正常 Normal				
24:00-01:00		人选 Manual sorted																	正常 Normal				
01:00-02:00		机选 Machine sorted																	正常 Normal				
02:00-03:00		人选 Manual sorted																	正常 Normal				
03:00-04:00		机选 Machine sorted																	正常 Normal				
04:00-05:00		人选 Manual sorted																	正常 Normal				
05:00-06:00		机选 Machine sorted																	正常 Normal				
06:00-07:00		人选 Manual sorted																	正常 Normal				
07:00-08:00		机选 Machine sorted																	正常 Normal				
合计: Total																			正常 Normal				
说明:本班尾数必须由下一班全部接收。								Note: On-duty shifts must take over the balance quantity left by the off duty shifts.															
备注:此生产记录常发生于各种活动,包括但不限于以下所列: 1.注塑机停机、调机; 2.自动线调整标签、换标签; 3.各种报警处理 4.改善措施执行(比如增加扇子风机、放大镜头); 5.注塑、自动线设备的修理、变更、零件替换等; 各种停机并标记为非生产活动,如设备停机、半生产、正常生产等; 6.当生产异常时,立即通知相关人员; 7.当生产正常时,在空白处标记为正常。此报告记录了所有正常生产运行,包括但不限于: 1.注塑机停机、调机; 2.自动线调整和更换; 3.各种报警处理; 4.线改进(如添加通风或放大器); 5.维修、变更、零件替换等; 6.机器故障; 7.当生产正常时,在空白处标记为正常。如果缺陷率超过5%,技术人员应立即停止改进。																							

生产特殊活动记录表

Special case records during production

处理方法Disposing methods

责任人签名PP Signature

时间 Time 原因 Cause of the problem

作业员Operator: 2023.12.30
Published on 2023-11-10 | MM 26 | DD 发布

文件类型 Document Type	质量记录 Quality Record
--------------------	---------------------

标题 Title	E2G 外包装检查记录表 E2G Inspection Record(outer packing)					
----------	---	--	--	--	--	--

产品名称 Name	Asay Tip/Asay Cup tray	批号 Batch No.	23003908				
生产日期 Manufacture Date	2024.01.02	检验日期 Inspection Date	2024.01.02				
		检验时间 Inspection Time					
		白班 <input checked="" type="checkbox"/>	08: 00-10: 00	10: 00-12: 00	12: 00-14: 00	14: 00-16: 00	16: 00-18: 00
名称 Name		夜班 <input type="checkbox"/>	20: 00-22: 00	22: 00-24: 00	24: 00-02: 00	02: 00-04: 00	04: 00-06: 00
组装 Assembly	外包装材料缺失 Missing outer packaging material	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	材料印刷不清晰、有误 Material printing is unclear and wrong	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
封箱 Sealing boxes	外包装材料破损 The outer packing material is damaged	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	胶带未覆盖定位标记或胶带超过了穿孔处 Tape does not cover the positioning mark or tape exceeds	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
堆垛 Stacking	标签未覆盖定位标记 The label does not overwrite the location tag	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	标签信息有误，内外标签批号、信息不一致 The label information is incorrect	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
外观 Appearance	未按 4×3=12 箱/棧板堆放 (4 张防滑纸) Not stacked according to 4x3 = 12 boxes per pallet with 4x anti-slip paper	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	表面脏污、异物等 Surface dirt, foreign matter, etc	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
其它 Other	其它 Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	不良次数 Number of failures	1	<input type="checkbox"/>				
统计 Statistics	良品次数 Number of good products	168	180	162	144	150	
	不良率 Defective rate	0.6%	0%	0%	0.7%	0.7%	

填写说明： Instructions:

- 需在“白班口”或“夜班口”处打上“√”代表作业员对应的班次。 1.A tick needs to be placed at "Day Shift" or "Night Shift" to indicate the corresponding shift of the operator.
- 填写栏记录不良数量，统计栏进行统计。 2.The number of defects is recorded in the filling field and counted in the statistical field.
- 不良率目标值≤3%，当超过3%时需立即上报主管处理。 Defective rate target value ≤3%, when more than 3% should be reported to the supervisor immediately.

作业员 operator/日期 Date: 柏松 何欢伟 · 2024.01.02
Published on 2023 年 YY 07 月 MM 13 日 DD 发布

P03

文件类型Doc Type	质量记录Quality Record
文件名称Doc Name	清拉检查表Line Cleaning Check Form

日期 Date:

2023.12.30

机台 Machine:

Line 29

生产命令单 Job No:

Any job -231200042

批号 Lot No:

230637908

序号 Item	检查内容 Check the content	责任人 Responsible	完成情况 Completion Status	检查人 Checked by	IPQC确认 Confirmed by
1	产品条形码 Barcode label	班长	N/A		
2	内袋标签 Inner box label	班长	√		
3	SOP 作业指导书	班长	√		
4	包装指导书 Packing SOP	班长	√		
5	品质文件/SIP Quality Document	班长	√	陈军 2023.12.30	王利国 2023.12.30
6	包材 Package material	班长	√		
7	人员安排 Arrangement of people	班长	√		
8	工作台清理 Cleaning of worktable	作业员	√		
9	注塑机、机械手、自动化清洁, 清理机台内余料 Cleaning of machines and Remove remaining material	技师	√		

注: Ok 写“√”, 不适用写“N/A”

保密等级: 敏感Confidentiality Level: Sensitive

Published on 2023 年 YY 10 月 MM 26 日 DD 发布

Executed on 2023 年 YY 10 月 MM 28 日 DD 实施

P03

ZHEJIANG BOCOMINGSHENG MEDICAL TECHNOLOGY CO., LTD.

浙江博明生医疗科技有限公司
Zhejiang Boomingsheng Medical Technology Co., Ltd.

文件编号
Doc No. ZB-QR-52010
版本号
Version 00

页码
Page 1 / 1

文件类型 Document Type	质量记录 Quality Record	入库单 Inbound Form
标题 Title	入库单号 Warehousing order number:	入库日期 Warehousing date:
仓库 Warehouse: 保税成品仓	ZBS041-24010003	2024-01-06
类别 Category: 产成品入库		部门 Department: 仓储组

生产订单号 Production order number	产品名称 Product name	规格型号 specifications and models	单位 Unit	应收数量 Quantity receivable	数量 Quantity	批号 Lot number	备注 Remarks
BMS0606-231200042	AssayTip/AssayCup tray	/	盒	4824	4824	230039008	/
合计 Amount to				4824	4824		

白联: 仓库 红联: PMC 黄联: 财务 White Union: Warehouse Red Union: PMC Yellow Union: Finance

制单人
Prepared by:

章伟峰 2024-01-06

审核人
Auditor:

134

P63

 浙江柏明胜医疗科技有限公司 Zhejiang Boomingshing Medical Technology Co.,Ltd. P103				文件名称 Doc. Name	标签过程检查记录表 Label Process Inspection Record Form			版本 Version	01	发布日期 Published on	2023年YY10月MM23日DD	
				文件类型 Doc.Type	质量记录 Quality Record	文件编号 Doc.No.	ZB-QR-12078			实施日期 Executed on	2023年YY10月MM24日DD	
品名 Name	Assay Tip/Assay Cup tray	批次 Lot	23003908	产品数量 Product QTY.	4824	条形码数量 Bar code QTY.	M/15	内袋标签数量 Primary label QTY.	821	外箱票数量 Second label Qty	136	
标签名称 Label name	序号 Order	首件标签留样 First label retention sample		序列号后5位 Serial number after 5 bits	末件标签留样 Final label retention sample		检查项目 Inspection Items	首件结果 Result	检查员/班长 Inspector / Monitor	末件结果 Result	检查员/班长 Inspector / Monitor	
产品 条形码 Barcode label	①	送检人Person for inspection: _____ 日期Date: _____		从From 到To	送检人Person for inspection: _____ 日期Date: _____		1. 生产日期 (标签上) _____ Production date: _____ 2. 有效期长: _____ Period of validity: _____	_____	_____	_____	_____	
	②	送检人Person for inspection: _____ 日期Date: _____		从From 到To	送检人Person for inspection: _____ 日期Date: _____		3. 失效日期: _____ Expiry date: _____ 4. 标签等级 1.5-4.0 _____ Grade 1.5-4.0: _____	_____	_____	_____	_____	
	③	送检人Person for inspection: _____ 日期Date: _____		从From 到To	送检人Person for inspection: _____ 日期Date: _____		5. 打印清晰/无断线/无脏污 Clear and legible/no short ink and dirt	_____	_____	_____	_____	
	④	送检人Person for inspection: _____ 日期Date: _____		从From 到To	送检人Person for inspection: _____ 日期Date: _____		6. 条形码扫描读数 (手写) Scan barcode and record readings: _____	_____	_____	_____	_____	
送检人Person for inspection: 张燕 日期Date: 2023.10.23 送检人Person for inspection: 张燕 日期Date: 2023.10.23				AssayTip/AssayCup tray   REF 05694302001 LOT 23003908 2025-11-30 CE IVD dialog.roche.com cobas®			AssayTip/AssayCup tray   REF 05694302001 LOT 23003908 2025-11-30 CE IVD dialog.roche.com cobas®			1. 生产日期 (标签上): _____ Production date: _____ N/A 2. 有效期长: _____ Period of validity: _____ 23个月 3. 失效日期: _____ Expired date: _____ 2025.11.30 4. 打印清晰/无断线/无脏污 Clear and legible/no short ink and dirt OK		

注: 1. 条码、内袋票、外箱票生产日期, 必须为同一个月份, 2. 条码与内袋票同时打印及送检。

Note: 1. The production date of bar code, primary and second label must be the same month. 2. Bar code and primary label should be printed and submitted for inspection at the same time.

AssayTip/AssayCup tray



 BOOMINGSHING MEDICAL 浙江柏明胜医疗科技有限公司 Zhejiang Boomingshing Medical Technology Co.,Ltd.			文件名称 Doc. Name Label Process Inspection Record Form 标签过程检查记录表			版本 Version 01			发布日期 Published on 2023年YY10月MM23日DD		
									实施日期 Executed on 2023年YY10月MM24日DD		
<p>(注: 1. 条码、内袋票、外箱票生产日期, 必须为同一个月份, 2.条码与内袋票同时打印及送检)</p> <p>Note: 1. The production date of bar code, inner bag ticket and outer box ticket must be the same month. 2. Bar code and inner bag ticket must be printed and submitted for inspection at the same time)</p>						<p>二维码组成: 由 (01) GTIN+(10)LOT号+(11)DOM 生产日期+(17)DOE有效期+(240)REF组成 QR code: composed of (01) GTIN + (10) LOT number + (11) DOM production date + (17) DOE period of valid + (240) REF</p>					
标签名称 Label name Inspection Items			P183 首件标签留样 First label retention sample			末件标签留样 Final label retention sample					
外箱标签 Carton label	1. 生产日期 (标签上) Production date: <i>2023.12.24</i>		For cobas e 801 analytical unit cobas e 402 analytical unit		REF (240) 05694302001 GTIN (01) 04015630928194 UDI		REF (240) 05694302001 GTIN (01) 04015630928194 UDI				
	2. 有效期长: Period of validity <i>23个月</i>		COBAS and COBAS E are trademarks of Roche		REF (240) 05694302001 GTIN (01) 04015630928194 UDI		REF (240) 05694302001 GTIN (01) 04015630928194 UDI				
	3. 失效日期: Expiry date: <i>2025.11.30</i>		Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim, Germany		REF (240) 05694302001 GTIN (01) 04015630928194 UDI		REF (240) 05694302001 GTIN (01) 04015630928194 UDI				
	4. 标签等级1.5-4.0 Grade 1.5-4.0 <i>4.0</i>		COBAS and COBAS E are trademarks of Roche		REF (240) 05694302001 GTIN (01) 04015630928194 UDI		REF (240) 05694302001 GTIN (01) 04015630928194 UDI				
	5. 打印清晰/无断线/ 无脏污 Clear and legible/no short ink and dirt <i>018</i>		Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim, Germany		REF (240) 05694302001 GTIN (01) 04015630928194 UDI		REF (240) 05694302001 GTIN (01) 04015630928194 UDI				
	6. 扫描读数 (手写) Scan barcode and record readings <i>(01)04015630928194(10)23003908</i>		Distributed in USA by: Roche Diagnostics 9115 Hague Road Indianapolis, Indiana USA		REF (240) 05694302001 GTIN (01) 04015630928194 UDI		REF (240) 05694302001 GTIN (01) 04015630928194 UDI				
	送检人 Person for inspection: <i>张晓波</i>		Made in China		REF (240) 05694302001 GTIN (01) 04015630928194 UDI		REF (240) 05694302001 GTIN (01) 04015630928194 UDI				
AssayTip/AssayCup tray						 cobas +2°C  +32°C					
For USA: Rx only						For USA: Rx only					
2023-12-24						2025-11-30					
36 AssayTip/AssayCup tray						3 Wasteliner					
20229050 CON 001 02						20229050 CON 001 02					
流程: 打票员首件/末件送检--IPQC检查--IPQC班长确认--结束。 Process: ticket first / last piece for inspection -- IPQC check -- IPQC monitor confirmation -- end						保密密级: 敏感 Confidentiality Level: Sensitive 2/2					

Omron Microscan Systems, Inc. LVS-95xx Verification Report

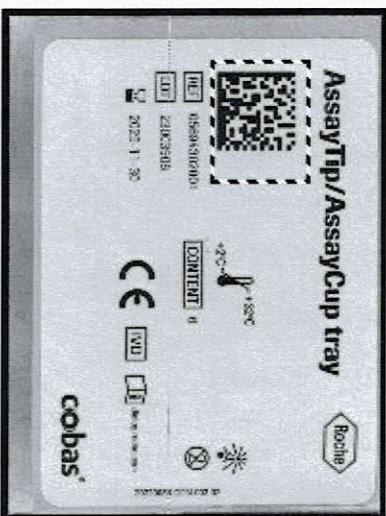
P63

Overall: 4.0/08/660/D

Reference: admin

2023.12.29
Operator signature
2023.12.29

Second signature



2D	
Symbology	GS1 Data Matrix
Decoded text	102300390817251130240056943020 01
Cell size	26.3 mils
Decode	PASS
Contrast	4.0 84%
Modulation	4.0
Reflectance margin	4.0
Axial nonuniformity	4.0 1.6%
Grid nonuniformity	4.0 6%
Unused EC	4.0 100%
Fixed pattern damage	4.0
L1 (left of L finder)	4.0
L2 (bottom of L finder)	4.0
QZL1 (left quiet zone)	4.0
QZL2 (bottom quiet zone)	4.0
CTR (clock track regularity)	4.0
CTD (clock track damage)	4.0
SFP (solid fixed pattern)	4.0
OCTASA (overall clock track and solid area)	4.0
AG (average grade)	4.0
TR (transition ratio)	4.00.00
Cell height	26.5 mils
Cell width	26.1 mils
Symbol Rotation	0 degrees
Sensor Angle	0 degrees
Light Direction	Red Dome
X print growth	52%
Y print growth	50%
Total CW	32
Data CW	18
Corrections	0
Size	18x18
Rmin	4.3%
Rmax	87.8%
Contrast uniformity	75%
Structure	PASS

Other information	
GS1 Data	(1)023003908(1)251130(240)056
GS1 Data Structure	94302001
Pass/Fail	PASS
Letter Grade	A
ReportID	3741
Operator	admin (LVS Administrator)
Application standard	GS1 General Specifications
GS1 Table	Table 1 - Trade Items Scanned in General Retail POS and not General Distribution
Limit Action	Change grade to F if Xdim or symbol height is outside limits
Effective aperture	Reference number 08 (7.95 mil)
Lighting	660/D
Date and time	29-Dec-2023 13:29 local; 29-Dec-2023 05:29 GMT
Time zone	GMT +8
Sector size	0.71"by 0.58"
Last calibration	11-Dec-2023 10:26 local; 11-Dec-2023 02:26 GMT
Field of view	3.03" (camera is 2592x1944 pixels)
Serial numbers	Unit: 2248426, Camera: 1222024
Software product and version	4, Model: 9580
LVS-95xx	LVS-95xx Version 4.4.3.4102
manufactured by:	Omron Microscan Systems, Inc.
	700 SW 39th Street, Ste. 100 Renton, WA 98057 USA
	http://www.microscan.com

2D Structure		
Embedded data	Description	Value
<232>	FNC1	
10	Batch or Lot Number	(10)
23003908	Batch or Lot Number	23003908
<232>	FNC1	
17	Expiration Date (YYMMDD)	(17)
251130	Expiration Date (YYMMDD)	251130
240	Additional Item Identification	(240)
05694302001	Additional Item Identification	05694302001

Omron Microscan Systems, Inc.

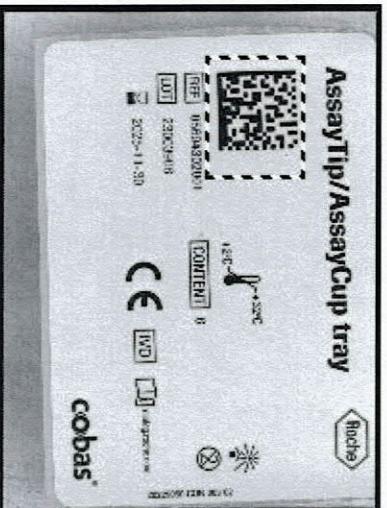
LVS-95xx Verification Report

P463

Overall: 4.0/08/660/D

Reference: admin

王 晓月 2023.12.29
Operator signature
2024.12.29



Second signature

2D	
Symbology	GS1 Data Matrix
Decoded text	102300390817251130240056943020
Cell size	01
Decode	26.5 mils
Contrast	PASS
Modulation	4.0 85%
Reflectance margin	4.0
Axial nonuniformity	4.0 0.5%
Grid nonuniformity	4.0 7%
Unused EC	4.0 100%
Fixed pattern damage	4.0
L1 (left of L finder)	4.0
L2 (bottom of L finder)	4.0
QZL1 (left quiet zone)	4.0
QZL2 (bottom quiet zone)	4.0
CTR (clock track regularity)	4.0
CTID (clock track damage)	4.0
SFP (solid fixed pattern)	4.0
OCTASA (overall clock track and solid area)	4.0
AG (average grade)	4.0
TR (transition ratio)	4.0 0.00
Cell height	26.6 mils
Cell width	26.4 mils
Symbol Rotation	-2 degrees
Sensor Angle	2 degrees
Light Direction	Red Dome
X print growth	52%
Y print growth	50%
Total CW	32
Data CW	18
Corrections	0
Size	18x18
Rmin	4.3%
Rmax	89%
Contrast uniformity	81%
Structure	PASS

Other information	
GS1 Data	(1)023003908(17251130(240)056
GS1 Data Structure	94302001
Pass/Fail	PASS
Letter Grade	A
ReportID	3786
Operator	admin (LVS Administrator)
Application standard	GS1 General Specifications
GS1 Table	Table 1 - Trade Items Scanned in General Retail POS and not General Distribution
Limit Action	Change grade to F if Xdim or symbol height is outside limits
Effective aperture	Reference number 08 (7.95 mil)
Lighting	660/D
Date and time	29-Dec-2023 14:35 local; 29-Dec-2023 06:35 GMT
Time zone	GMT +8
Sector size	0.71" by 0.58"
Last calibration	11-Dec-2023 10:26 local; 11-Dec-2023 02:26 GMT
Field of view	3.03" (camera is 2592x1944 pixels)
Serial numbers	Unit: 2248426, Camera: 1222024
Software product and version	4, Model: 9580
LVS-95xx	LVS-95xx Version 4.4.3.4102
manufactured by:	Omron Microscan Systems, Inc. 700 SW 39th Street, Ste. 100 Renton, WA 98057 USA http://www.microscan.com

2D Structure		
Embedded data	Description	Value
<232>	FNC1	
10	Batch or Lot Number	(10)
23003908	Batch or Lot Number	23003908
<232>	FNC1	
17	Expiration Date (YYMMDD)	(17)
251130	Expiration Date (YYMMDD)	251130
240	Additional Item Identification	(240)
05694302001	Additional Item Identification	05694302001

Omron Microscan Systems, Inc.

LVS-95xx Verification Report

P403

Overall: 4.0/08/660/D

Reference: admin

J. AKAH 2023.12.29
Operator signature

J. AKAH 2023.12.29
Second signature

Tray	
REF	(240) 05694302001
GTIN	(01) 04015630928194
LOT	(10) 23003908
	
	2025-11-30
	2023-12-24
Count	36 AssayTip/AssayCup tray
	3 Wasteline

2D		Other information
Symbology	GS1 Data Matrix	(01) 04015630928194 (10) 23003908
Decoded text	010401563092819410230039081123	(11) 231224(17) 251130(240) 05694
Cell size	12.241725113024005694302001	302001
Decode	PASS	GS1 Data Structure
Contrast	4.0 75%	Pass/Fail
Modulation	4.0	Letter Grade
Reflectance margin	4.0	A
Axial nonuniformity	4.0 0.6%	ReportID
Grid nonuniformity	4.0 10%	Operator
Unused EC	4.0 100%	admin (LVS Administrator)
Fixed pattern damage	4.0	Application standard
L1 (left of L finder)	4.0	GS1 Table
L2 (bottom of L finder)	4.0	GS1 General Specifications
QZL1 (left quiet zone)	4.0	Table 1 - Trade Items Scanned
QZL2 (bottom quiet zone)	4.0	in General Retail POS and not
CTR (clock track regularity)	4.0	symbol height is outside limits
CTD (clock track damage)	4.0	General Distribution
SFP (solid fixed pattern)	4.0	Change grade to F if Xdim or s
OCTASA (overall clock track and	4.0	ymbol height is outside limits
solid area)		Reference number 08 (7.95 mil)
AG (average grade)	4.0	Effective aperture
TR (transition ratio)	4.0 0.00	Lighting
Cell height	21.7 mils	660/D
Cell width	21.6 mils	Date and time
Symbol Rotation	0 degrees	29-Dec-2023 14:57 local; 29-Dec
Sensor Angle	0 degrees	c-2023 06:57 GMT
Light Direction	Red Dome	Time zone
X print growth	55%	GMT +8
Y print growth	53%	Sector size
Total CW	50	0.69" by 0.70"
Data CW	30	Last calibration
Corrections	0	11-Dec-2023 10:26 local; 11-Dec
Size	22x22	c-2023 02:26 GMT
Rmin	5.1%	Field of view
Rmax	79.6%	3.03" (camera is 2592x1944 pixels)
Contrast uniformity	69%	Serial numbers
Structure	PASS	Unit: 2248426, Camera: 1222024

Other information	
GS1 Data	(01) 04015630928194 (10) 23003908
GS1 Data Structure	(11) 231224(17) 251130(240) 05694
Pass/Fail	PASS
Letter Grade	A
ReportID	3823
Operator	admin (LVS Administrator)
Application standard	GS1 General Specifications
GS1 Table	Table 1 - Trade Items Scanned
GS1 General Specifications	in General Retail POS and not
Table 1 - Trade Items Scanned	symbol height is outside limits
in General Retail POS and not	General Distribution
symbol height is outside limits	Change grade to F if Xdim or s
General Distribution	ymbol height is outside limits
Change grade to F if Xdim or s	Reference number 08 (7.95 mil)
ymbol height is outside limits	Effective aperture
Reference number 08 (7.95 mil)	Lighting
Effective aperture	660/D
Lighting	Date and time
660/D	29-Dec-2023 14:57 local; 29-Dec
Date and time	c-2023 06:57 GMT
29-Dec-2023 14:57 local; 29-Dec	Time zone
c-2023 06:57 GMT	GMT +8
Time zone	Sector size
GMT +8	0.69" by 0.70"
Sector size	Last calibration
0.69" by 0.70"	11-Dec-2023 10:26 local; 11-Dec
Last calibration	c-2023 02:26 GMT
11-Dec-2023 10:26 local; 11-Dec	Field of view
c-2023 02:26 GMT	3.03" (camera is 2592x1944 pixels)
Field of view	Serial numbers
3.03" (camera is 2592x1944 pixels)	Unit: 2248426, Camera: 1222024
Serial numbers	4. Model: 9580
Unit: 2248426, Camera: 1222024	Software product and
4. Model: 9580	version
Software product and	LVS-95xx Version 4.4.3.4102
version	Omron Microscan Systems, Inc.
LVS-95xx	700 SW 39th Street, Ste. 100
manufactured by:	Renton, WA 98057 USA
http://www.microscan.com	

2D Structure		
Embedded data	Description	Value
<232>	FNC1	
01	Global Trade Item Number (GTIN)	(01)
04015630928194	Global Trade Item Number (GTIN)	04015630928194
))
10	Batch or Lot Number	(10)
23003908	Batch or Lot Number	23003908
<232>	FNC1	
11	Production Date (YYMMDD)	(11)
231224	Production Date (YYMMDD)	231224
17	Expiration Date (YYMMDD)	(17)
251130	Expiration Date (YYMMDD)	251130
240	Additional Item Identification	(240)
05694302001	Additional Item Identification	05694302001

Omron Microscan Systems, Inc.

LVS-95xx Verification Report

rho3

Overall: 4.0/08/660/D

Reference: admin

[REF]	(240) 05694302001	[UDI]
[Gtin]	(01) 04015630928194	
[Lot]	(10) 23003908	
[Date]	2025-11-30	
[Content]	36 AssayTip/AssayCup tray	
	3 Wasteline	

2231060 CCN 02102

王 晓 希 2023. 12.29

Operator signature

王 晓 希 2023. 12.29

Second signature

2D	
Symbology	GS1 Data Matrix
Decoded text	010401563092819410230039081123 12241725113024005694302001
Cell size	21.6 mils
Decode	PASS
Contrast	4.0 74%
Modulation	4.0
Reflectance margin	4.0
Axial nonuniformity	4.0 0.9%
Grid nonuniformity	4.0 10%
Unused EC	4.0 100%
Fixed pattern damage	4.0
L1 (left of L finder)	4.0
L2 (bottom of L finder)	4.0
QZL1 (left quiet zone)	4.0
QZL2 (bottom quiet zone)	4.0
CTR (clock track regularity)	4.0
CTID (clock track damage)	4.0
SFP (solid fixed pattern)	4.0
OCTASA (overall clock track and solid area)	4.0
AG (average grade)	4.0
TR (transition ratio)	4.0 0.00
Cell height	21.5 mils
Cell width	21.7 mils
Symbol Rotation	0 degrees
Sensor Angle	0 degrees
Light Direction	Red Dome
X print growth	56%
Y print growth	55%
Total CW	50
Data CW	30
Corrections	0
Size	22x22
Rmin	5.1%
Rmax	79.2%
Contrast uniformity	69%
Structure	PASS

Other information	
GS1 Data	(01)04015630928194(1023003908 (11)231224(17)251130(240)05694 302001
GS1 Data Structure	PASS
Pass/Fail	
Letter Grade	A
ReportID	3843
Operator	admin (LVS Administrator)
Application standard	GS1 General Specifications
GS1 Table	Table 1 - Trade Items Scanned in General Retail POS and not General Distribution
Limit Action	Change grade to F if Xdim or s ymbol height is outside limits
Effective aperture	Reference number-08 (7.95 mil)
Lighting	660/D
Date and time	29-Dec-2023 15:37 local; 29-Dec c-2023 07:37 GMT
Time zone	GMT +8
Sector size	0.64" by 0.59"
Last calibration	11-Dec-2023 10:26 local; 11-De c-2023 02:26 GMT
Field of view	3.03" (camera is 2592x1944 pix els)
Serial numbers	Unit: 2248426, Camera: 1222024 4. Model: 9580
Software product and version	LVS-95xx Version 4.4.3.4102
LVS-95xx manufactured by:	Omron Microscan Systems, Inc. 700 SW 39th Street, Ste. 100 Renton, WA 98057 USA http://www.microscan.com

2D Structure		
Embedded data	Description	Value
<232>	FNC1	
01	Global Trade Item Number (GTIN)	(01)
04015630928194	Global Trade Item Number (GTIN)	04015630928194
<232>	FNC1	
10	Batch or Lot Number	(10)
23003908	Batch or Lot Number	23003908
<232>	FNC1	
11	Production Date (YYMMDD)	(11)
231224	Production Date (YYMMDD)	231224
17	Expiration Date (YYMMDD)	(17)
251130	Expiration Date (YYMMDD)	251130
240	Additional Item Identification	(240)
05694302001	Additional Item Identification	05694302001

文件名称 Doc. Name	产品首/末件确认单 Product First/Last Piece Confirmation	版本 Version	01
文件类型 Doc. Type	质量记录 Quality Record	文件编号 Doc.No.	页码 Page
<input checked="" type="checkbox"/> 首件检查 First piece inspection			□ 修模后首件 The first piece after mold repair
<input type="checkbox"/> 末件检查 Final piece inspection			□ 试产模具首件 The first mold in trial production

日期 Date:	2023.12.24	生产命令单 Job No.:	2B50022-231200012	批次号 Lot No.:	S231200022
机台号 Machine No.:	2B-K-31-02V	模具编号 Mould No.:	CH20220850	品名 product name:	Assay-rack plain
原材料名称 Material	MPS ACM MED PS100	原材料批次号 Raw material batch no.:	0122W48804	产品日期章 Date Seal:	2023.12

The manufacturing department checks the contents								
送检次数 Inspected Times	结构 Structure	外观检查 Appearance Inspection	修模问题点 Repair mold problem point	修模后效果确认 effect after mold repair	判定结果 Result	送检人 Inspector	判定人 Primary Inspector	送检时间 Inspection Time
第一次First Time	OK	OK	N/A	N/A	OK	王威	王威	08:16
第二次Second Time				N	A			
第三次Third Time								

质量部检查内容								
确认次数 Confirmation Times	尺寸 Dimension	外观检查 Appearance Inspection	修模问题点 Repair mold problem point	修模后效果确认 effect after mold repair	判定结果 Result	送检人 Inspector	判定人 Primary Inspector	送检时间 Inspection Time
第一次 First Time	实测尺寸见 首件尺寸报 表See the first size report for measured dimensions	OK	OK	N/A	OK	N/A	OK	王威 2023.12.24 08:16
第二次 Second Time				N	A			
第三次 Third Time								

不符合项原因分析 Cause analysis of nonconformance item :

不符合项改善对策 Improvement measures for nonconformance item s:

分析人/日期 Analyze the person/date:

N/A

N/A

N/A

首件开机条件作业标准 (末件检查不适用)

Operation standard for first article start-up conditions (Final inspection is not applicable)

开机条件

Technician confirmation

IPOC确认 Dept.

- 确认人员是否有资格认证或对产品是否熟悉，
Check that operator is certified or acquainted with products.
 - 有无注塑参数工艺卡、对应产品作业指导书、品质检验标准等资料，
Check that there are moulding specific sheet, corresponding SOP and IP, etc.
 - 取出方式 (全自动脱模/机械手取出半自动) 是否与作业指导书相符，机械手取出产品有无干涉和碰伤，
Check that take-out method(full-automatic/mechanical arm semi-automatic) is consistent with SOP, and products grabbed out by mechanical arm exist scratch and hit.
 - 模具是否有修理和变动，有无确认，
Check that the mould is repaired and changed, make a confirmation?
 - 确认注塑参数点检记录、机台上实际参数与成型工艺三者是否一致，
Confirm whether the spot check record of injection parameters, actual parameters on the machine and the moulding process card are consistent.
 - 原材料使用是否按照要求？原料标签信息是否记录完整，
Check that raw materials are used as requested? The material information on the label is complete.
 - 确认机台上 (机台附近) 清场是否彻底，是否有上款产品或物料标签，标签信息是否正确，
Check that line clearance is complete, there are any previous products or their labels, and information on the label is correct.
 - 确认机台及自动化情况是否符合生产含要求，
Check that machine and automatic meet the requirements of production.
- 备注：首件开机条件作业标准确认合格打“√”，不合格打“✗”，未完成打“/”，已修改打“△”
Note: Operation standard for first article start-up conditions--qualified“√”, failed“✗”, not completed“/”, modified“△”
- 第一联(白) 质量部存档，第二联(红)，和首件挂机台，1st page for Quality Dept(White), 2nd page for Molding Dept(Read)
Sensitive
Published on 2023年12月23日 00:00 发布

广东新嘉隆塑料有限公司 Guangdong Xingjialong Plastic Co., Ltd.	文件名称 Doc. Name	产品首/末件确认单 Product First/Last Piece Confirmation	版本 Version	01
机台号 Machine No.	文件类型 Doc. Type	质量记录 Quality Record	文件编号 Doc.No.	ZB-SR-12071 Page
原材料名称 Material	产品日期章 Date Seal:	产品名 product name:	批次号 Lot No.	S23120006 Assyory -rank Plain

首件检查 First piece inspection

试模后首件 The first piece after mold repair

P03

日期 Date,	2023.12.24	生产命令单 Job No:	28S002 - 231200012	批次号 Lot No,	S23120006
机台号 Machine No,	模具编号 Mould No,	CM 202208510	品名 product name:	AS/NUS	Assyory -rank Plain
原材料名称 Material	原材料批次号 Raw material batch no :	0122W48804	产品日期章 Date Seal:	2023.12	

制造部检查内容

送检次数 Inspected Times	尺寸 Dimension	外观检查 Appearance Inspection	结构 Structure	测试实验 Test	修模问题点 Repair mold problem point	修模后效果确认 Confirm the effect after mold repair	判定结果 Result	送检人 Inspector	初判人 Primary Inspector	送检时间 Inspection Time
第一次 First Time	OK	OK	N/A	N/A			OK	黄晓月	黄晓月	2023.12.24
第二次 Second Time				N						
第三次 Third Time				A						

质量部检查内容

确认次数 Confirmation Times	尺寸 Dimension	外观检查 Appearance Inspection	结构 Structure	测试实验 Test	组装检查 Assembly Check	客户问题确认 Customer complaint problem confirmation	修模后效果确认 Confirm the effect after mold repair	判定结果 Result	判定人 Inspector	班组长确认 Confirm	回复时间 Reply Time
第一次 First Time	OK	OK	N/A	OK	N/A	N/A	N/A	OK	黄晓月	黄晓月	2023.12.24
第二次 Second Time	first size report for measured			N							
第三次 Third Time	dimensions			A							

不符合项原因分析 Cause analysis of nonconformance item :

N/A

首件开机条件作业标准 (末件检查不适用)

Operation standard for first article start-up conditions (Final inspection is not applicable)

开机条件

Start-up conditions

技术员确认
Technician confirmation

IPOC确认
Confirmed by quality Dept.

- 确认人员是否有资格认证或对产品是否熟悉;
Check that operator is certified or acquainted with products.
- 有无注塑参数工艺卡、对应产品作业指导书、品质检验标准等资料;
Check that there are moulding specific sheet, corresponding SOP and SIP etc.
- 取出方式 (全自动脱模/半自动) 是否与作业指导书相符, 模具手取出产品有无干涉和碰伤;
Check that take-out method(full-automatic/mechanical arm, semi-automatic) is consistent with SOP, and products grabbed out by mechanical arm exist scratch and hit.
- 模具是否有修理和变动, 有无确认;
Check that the mould is repaired and changed, make a confirmation?
- 确认塑参数点检记录、机台上实际参数与成型工艺卡三者是否一致;
Confirm whether the spot check record of injection parameters, actual parameters on the machine and the molding process card are consistent.
- 原材料使用是否按照要求? 原料标签信息是否记录完整;
Check that raw materials are used as requested? The material information on the label is complete.
- 确认机台上 (机台附近) 清场是否彻底, 是否有上款产品或物料标签, 标签信息是否正确;
Check that line clearance is complete, there are any previous products or their labels, and information on the label is correct.
- 确认机台及自动化5S情况是否符合生产含要求;
Check that 5S of machine and automatic meet the requirements of production.

备注: 首件开机条件作业标准确认合格打“√”, 不合格打“✗”;

Note: Operation standard for first article start-up conditions - qualified "√", failed "✗"

开机条件不符合说明 Boot conditions are not specified

第一联 (白) 质量部存档, 第二联 (红), 和首件挂在机台, 1st page for Quality Dept(White), 2nd page for Molding Dept(Red)

Published on 2023年11月MM 23日 DD 发布
Sealed on

保密度级: 非密 Confidentiality Level:

Published on 2023年11月MM 24日 DD 实施

BOOMINGSHING MEDICAL 浙江柏明胜医疗科技有限公司 Zhejiang Boomingshing Medical Technology Co.,Ltd.						文件名称 Doc. Name	过程检查记录表 Process Inspection Record Form				版本 Version	01	发布日期 Published on	2023年YY10月 MM23日DD
						文件类型 DOC.Type	质量记录 Quality Record	文件编号 Doc.No.	ZB-QR-12051	页码 Page	1/1	实施日期 Executed on	2023年YY10月 MM24日DD	
机台号 Machine No:		生产命令单 Job No:		品名 Name:		产品日期章 Date Seal:		产品阶段 Product phase:						
Mould No:		Lot No:		模具穴数 Mold cavity:		Raw material batch lots:		OQ阶段 OQ phase: 中值Nom□ 高值Max□ 低值Min□						
检查项目 Inspection item		白班/Day shift						夜班/Night shift						
		08:00-10:00	10:00-12:00	12:00-14:00	14:00-16:00	16:00-18:00	18:00-20:00	20:00-22:00	22:00-0:00	0:00-2:00	02:00-4:00	04:00-6:00	06:00-8:00	
机台巡检 按SIP、工程样板、限度板等 Machine inspection according to relevant Standard Inspection Procedure,Gold sample&limit board, etc	核对首件FAI check	OK	OK	OK	OK	OK	OK							
	材料/颜色 Material/color	OK	OK	OK	OK	OK	OK							
	外观检查 Appearance check	OK	OK	OK	OK	OK	OK				N			
	条码标签检查 Barcode label check	N/A	N/A	N/A	N/A	N/A	N/A				A			
	包装袋/标签检查 Packing label check	N/A	N/A	N/A	N/A	N/A	N/A							
	包装检查 Packing check	OK	OK	OK	OK	OK	OK							
	尺寸 Dimension	See attached dimension report												
巡检异常处理 Abnormal dispose:	结构/试装 Structure/assembly	OK	OK	OK	OK	OK	OK							
	是否隔离或开异常单 Is product quarantined or deviation released?	N/A	N/A	N/A	N/A	N/A	N/A							
2H抽查结果 2H Sampling result:	生产负责人确认 Confirmation of production leader	N/A	N/A	N/A	N/A	N/A	N/A							
	2小时生产批量数 2H production QTY	614	862	810	872	780	854	142			N			
	IPQC抽样数量 IPQC sample size	80	80	80	80	80	80	20			A			
	抽查不良描述/数量 NC description /QTY	0	0	0	0	0	0	0						
	判定结果 Judgement result	OK	OK	OK	OK	OK	OK							
	不合格品处理方式 Disposal of NC products	N/A	N/A	N/A	N/A	N/A	N/A							
备注 Remark:	外观不良描述 Description of poor appearance: 色差Color deviation、缩水Shrinkage、缺胶Short shot、多胶Extra material、披锋/毛边Flash、变形Deform、夹水线/熔接痕Weld line、黑点Black point、混色Mixed color、烧焦Burned mark、气泡Bubble、裂痕Crack、压伤/划痕Scratch mark、困气air trapping、冷料发白White mark、油污Oil mark、胶位厚薄不均Uneven thickness、粘附异物Contaminated、雾面Matt mark、包装袋烂Bag damage、标签贴反Label stick on wrong direction、标签贴歪Label slant、漏贴标签Missing label、混料Mixed product、抛光不良Poor Polish、产品结构不符Structure deviation、段差/台阶Segment difference 判定结果Judgement result: 合格/OK 退货/Reject 返工/Rework 让步接收/AOD 报废/Scrap													
	P102		N/A											
白班QC/日期 Day shift QC/Date:		审核/日期 Checked by/Date:		夜班QC/日期 Night shift QC/Date:		审核/日期 Checked by/Date:								
<p>巡检标准：外观：1次/2H，尺寸：1吋/4H，按照对应产品的SIP。如客户有要求则以客户要求为准。 Inspection standard: Appearance: once / 2H, size: 1inch / 4H. According to the Quality Inspection Standards of the corresponding products. If the customer has any requirements, the customer shall prevail. 异常处理：IPQC 巡检发现品质异常，第一次先口头通知生产班长或技术员进行改善，在IPQC报告上确认签名，2H后无改善效果的，IPQC则开出书面“品质异常联系单”。 If IPQC inspection finds abnormal quality, the production monitor or technician will be orally notified to improve the quality for the first time, and the IPQC will confirm the signature on the IPQC report. If there is no improvement effect after 2 hours, IPQC will issue a written "Contact Sheet for abnormal Quality". 保密密级：敏感Confidentiality Level: Sensitive </p>														

文件名	产品首/末件确认单	版本	01									
Doc. Name	Product First/Last Piece Confirmation	Version										
文件类型	质量记录	页码	1/1									
Doc. Type	Quality Record	Page										
□首件检查First piece inspection □修模后首件 The first piece after mold repair □试模首件The first mold in trial production												
日期	2023.12.30	生产命令单 Job No:	203002-231200010 Lot No:									
机台号 Machine No:	2B-K-31-020	模具编号 Mould No:	CH2022087D product name:									
原材料名称 Material	PP PRE-ELEC TRIM	原材料批次号 Raw-material batch no:	9065 Date Seal:									
制造部检验内容 The manufacturing department checks the contents												
送检次数 Inspected Times	结构 Structure	外观检查 Appearance Inspection	维修问题点 Repair mold problem point									
第一次 First Time	OK	OK	N/A									
第二次 Second Time			N									
第三次 Third Time			A									
质量部检查内容 Check Contents of Quality Department												
确认次数 Confirmation Times	尺寸 Dimension	外观检查 Appearance Inspection	结构 Structure	测试实验 Test	组装检查 Assembly Check	客户问题确认 Customer complaint problem confirmation	修模后效果确认 Confirm the effect after mold repair	判定结果 Result	判定人 Inspector	判定人 Primary Inspector	班长确认 Confirm	回复时间 Reply Time
第一次 First Time	首件尺寸见表 See the first size report	OK	OK	N/A	N/A	N/A	OK	OK	王海	王海	09:30	
第二次 Second Time	报告尺寸 Report for measured dimensions				N							
第三次 Third Time					A							
不符合项原因分析Cause analysis of nonconformance item :				不符合项改善对策Improvement measures for nonconformance items:				分析人/日期Analyze the person/date:				
				N/A				N/A				
首件开机条件作业标准 (末件检查不适用) Operation standard for first article start-up conditions (Final inspection is not applicable)												
开机条件 Start-up conditions				技术员确认 Technician confirmation				IPQC确认 IPQC confirmed by quality Dept.				
1.确认人员是否有资格认证或对产品是否熟悉 Check that operator is certificated or acquainted with products.				√				√				
2.有无注塑参数工卡、对应产品作业指导书、品质检验标准等资料 Check that there are moulding specific sheet, corresponding SOP and SP, etc.				√				√				
3.取出方式 (全自动脱模/机械手取出半自动) 是否与作业指导书相符, 机械手取出产品有无干涉和碰伤; Check that take-out method(full-automatic/mechanical arm semi-automatic) is consistent with SOP, and products grabbed out by mechanical arm exist scratch and hit.				√				√				
4.模具是否有修理和变动, 有无缺料 Check that the mould is repaired and changed, make a confirmation?				√				√				
5.确认注塑参数记录、机台上实际参数与成型工艺卡三者是否一致; Confirm whether the spot check record or injection parameters, actual parameters on the machine and the molding process card are consistent.				√				√				
6.原料耗用是否按照要求? 原料标签信息是否记录完整 Check that raw materials are used as requested? The material information on the label is complete.				√				√				
7.确认机台上 (机台附近) 清场是否彻底, 是否有上料产品或物料标签, 标签信息是否正确 Check that line clearance is complete, there are any previous products or their labels, and information on the label is correct.				√				√				
备注: 首开机条件作业标准确认合格打“√”, 不合格打“✗”, 失格“✗” Note: Operation standard for first article start-up conditions - qualified “✓”, unqualified “✗”, failed “✗”				技术员Technician: 王海				IPQC: 王海				
开机条件不符号说明Boot conditions are not specified:												
第一联(白)质量部存档, 第二联(红): 和首件挂机台, 1st page for Quality Dept(white), 2nd page for Molding Dept(red)												
Sensitive Published on 2023年10月MM 25日DD 发布 Executed on 2023年10月MM 24日DD 实施												

上海三一塑料有限公司	上海三一塑料有限公司 Shanghai Sunyi Plastic Co., Ltd.	文件名称	产品首/末件确认单 Product First/Last Piece Confirmation	版本	01
Doc. Name	Quality Record	文件编号	ZS-QR-12071	页码	1/1

日期	2023.12.30	生产命令单	285002-231200010	批次号	24003908
机台号	2B-K-31-0020	模具编号	CH2022087D	品名	Assy-EPP
原材料名称	PP PRE-ELEC TR 1000	原材料批次号	90665	产品日期章	N/A

首件检查 First piece inspection

修模后首件 The first piece after mold repair

末件检查 Final piece inspection

试产模具首件 The first mold in trial production

P03

质量部检查内容								
送检次数 Inspected Times	尺寸 Dimension	外观检查 Appearance Inspection	结构 Structure	修复问题点 Repair mold problem point	修模后效果确认 Confirm the effect after mold repair.	判定结果 Result	送检人 Inspector	初判人 Primary Confirmator
第一次 First Time	OK	OK	N/A	N/A	OK	无法判断 无法判断	李继伟 22-18	
第二次 Second Time					N			
第三次 Third Time					A			

不符合项原因分析 Cause analysis of nonconformance item:

N/A

N/A

N/A

首件开机条件作业标准 (末件检查不适用) Operation standard for first article start-up conditions (First inspection is not applicable)

开机条件 Start-up conditions

技术员确认
Technician confirmation

IPOC确认
Confirmed by quality Dept.

1.确认人员是否有资格认证或对产品是否熟悉? Check that operator is certificated or acquainted with products.	
2.有无注塑参数(工艺卡、对应产品作业指导书、品质检验标准等资料) Check that there are moulding specific sheet, corresponding SOP and SPC etc.	
3.取出方式 (全自动脱模/机械手取出/半自动) 是否与作业指导书相符, 机械手取出产品有无干涉和碰伤; Check that take-out method(full-automatic, mechanical arm, semi-automatic) is consistent with SOP, and products grabbed out by mechanical arm exist scratch and hit.	
4.模具是否有修理和变动, 有无确认? Check that the mould is repaired and changed, make a confirmation?	
5.确认注塑参数记录、机台上实际参数与成型工艺卡三者是否一致? Confirm whether the spot check record of injection parameters, actual parameters on the machine and the molding process card are consistent.	
6.原材料使用是否按照要求? 原料标签信息是否记录完整? Check that raw materials are used as requested? The material information on the label is complete.	
7.确认机台上 (机台附近) 清场是否彻底, 是否有上款产品或物料标签, 标签信息是否正确? Check that line clearance is complete, there are any previous products or their labels, and information on the label is correct.	
8.确认机台及自动化情况是否符合生产需求? Check that the machine and automatic meet the requirements of production.	

备注: 首件开机条件作业标准确认合格打“√”，不合格打“✗”; Note: Operation standard for first article start-up conditions - qualified “√”, failed “✗”	
开机条件不 合 格说明 Boot conditions are not specified:	

第一联 (白) 质量部存档, 第二联 (红), 和首件挂在机台, 1st page for Quality Dept(white), 2nd page for Molding Dept(red)
Sensitive
Published on 2023年11月23日 00:00

保密密级: 敏感Confidentiality Level:

Published on 2023年11月23日 00:00

Executed on 2023年11月24日 00:00

文件名	产品首/末件确认单		版本	01	
Doc. Name	Product First/Last Piece Confirmation		Version		
文件类型	质量记录	文件编号	ZS-SR-12071	页码	
Doc. Type	Quality Record	Doc. No.		Page	
日期 Date,	2023/12/30	生产命令单 Job No:	2850602-23200013	批次号 Lot No:	2303908
机台号 Machine No.,	2B-K-31-021	模具编号 Mould No.,	CN2022086D	品名 product name:	Assay-Cup
原材料名称 Material	PP BRANED™ R7800W	原材料批次号 Raw material batch no.:	B2-230230	产品日期章 Date Seal:	N/A
制造部检查内容 The manufacturing department checks the contents					
送检次数 Inspected Times	结构 Structure	外观检查 Appearance Inspection	修模问题点 Repair mold problem point	修模后效果确认 Confirm the effect after mold repair	判定结果 Result
第一次First Time	OK	OK	N/A	N/A	OK
第二次Second Time				N	
第三次Third Time				A	
质量部检查内容 Check Contents of Quality Department					
确认次数 Confirmation Times	尺寸 Dimension	外观检查 Appearance Inspection	结构 Structure	测试实验 Test	组装检查 Assembly Check
第一次 First Time	首件尺寸报表 See the first size report for measured dimensions	OK	OK	N/A	N/A
第二次 Second Time				N	
第三次 Third Time				A	
不符合项原因分析 Cause analysis of nonconformance item:					
不符合项改善对策 Improvement measures for nonconformance item's:					
分析人/日期 Analyze the person/date:					
N/A					
首件开机条件作业标准 (末件检查不适用) Operation standard for first article start-up conditions (Final inspection is not applicable)					
开机条件 Start-up conditions		技术员确认 Technician confirmation	IPQC确认 Confirmed by quality Dept.		
1.确认人员是否有资格认证或对产品是否熟悉: Check that operator is certificate or acquainted with products.		√	√		
2.有关注塑参数工艺卡、对应产品作业指导书、品质检验标准等资料: Check that there are moulding specific sheet, corresponding SOP and SPC,etc.		√	√		
3.取出方式(全自动脱模/机械手取出半自动)是否与作业指导书相符, 机械手取出产品有无干涉和碰伤, Check that take-out method(full-automatic, mechanical arm, semi-automatic) is consistent with SOP, and products grabbed out by mechanical arm exist scratch and hit.		√	√		
4.模具是否有修理和变动, 有无确认: Check that the mould is repaired and changed, make a confirmation?		√	√		
5.确认注塑参数点检记录、机台上实际参数或成型工艺卡三者是否一致: Confirm whether the spot check record of injection parameters, actual parameters on the machine and the molding process card are consistent;		√	√		
6.原材料使用是否按照要求? 原料桥签信息是否记录完整: Check that raw materials are used as requested? The material information on the label is complete.		√	√		
7.确认机台上(机台附近)清场是否彻底, 是否有上款产品或物料标签, 标签信息是否正确: Check that line clearance is complete, there are any previous products or their labels, and information on the label is correct.		√	√		
8.确认机台及自动化情况是否符合生产要求: Check that the machine and automation meet the requirements of production.		√	√		
备注: 首件开机条件作业标准确认合格打"√", 不合格打"✗"; Note: Operation standard for first article start-up conditions.. qualified "✓", failed "✗".		技术员 Technican: 肖立伟	IPQC: 王丽娟		
第一联(白) 质量部存档, 第二联(红), 和首件挂在机台, 1st page for Quality Dept(White), 2nd page for Molding Dept(Red)					
敏感级别: 敏感 Confidentiality Level: 保密度级: 敏感 Confidentiality Level: 保密等级: 敏感 Confidentiality Level:					
Published on 2023年12月23日 DD 发布 Executed on 2023年12月 MM 24日 DD 完成					

首件检查 First piece inspection
 修模后首件 The first piece after mold repair

末件检查 Final piece inspection
 试产模具首件 The first mold in trial production

Plastic Molding Department

日期 Date:	2021.12.30	生产命令单 Job No.:	2B5D62-23120703	批次号 Lot No.:	23002908
机台号 Machine No.:	ZB-K-31-0021	模具编号 Mould No.:	CN120220860	品名 product name:	Assay-cup
原材料名称 Material	PP BLOWN M PEGASMO	原材料批次号 Raw material batch no.:	B2-230230	产品日期章 Date Seal:	N/A

制造部检查內容 The manufacturing department checks the contents

确认次数 Inspected Times	尺寸 Dimension	外观检查 Appearance Inspection	结构 Structure	测试实验 Test	修模问题点 Repair mold problem point	修模后效果确认 Confirm the effect after mold repair	判定结果 Result	送检人 Inspector	判定人 Primary Confirm	班长确认 Confirm	回复时间 Reply Time
第一次 First Time	OK	OK	N/A	N/A	N/A	OK	OK	王云涛	李维峰	2021.12.30	
第二次 Second Time											
第三次 Third Time											

不符合项原因分析 Cause analysis of nonconformance item :

不符合项改善对策 Improvement measures for nonconformance item :

分析人/日期 Analyze the person/date:

N/A

N/A

N/A

首件开机条件作业标准 (末件检查不适用) Operation standard for first article start-up conditions (Final inspection is not applicable)

开机条件 Start-up conditions	技术员确认 Technician confirmation	IPOC确认 Confirmed by quality Dept.
N/A		

- 确认人员是否有资格认证或对产品是否熟悉;
Check that operator is certified or acquainted with products.
- 有无注塑参数工艺卡、对应产品作业指导书、品质检验标准等资料;
Check that there are moulding specific sheet, corresponding SOP and SP, etc.
- 取出方式(全自动脱模/机械手取出/半自动)是否与作业指导书相符, 机械手取出产品有无干涉和碰伤;
Check that take-out method(full-automatic,mechanical arm,semi-automatic) is consistent with SOP, and products grabbed out by mechanical arm exist scratch and hit.
- 模具是否有修理和变动, 有无确认;
Check that the mould is repaired and changed, make a confirmation?
- 确认注塑参数点检记录、机台上实际参数与成型工艺卡三者是否一致;
Confirm whether the spot check record of injection parameters, actual parameters on the machine and the molding process card are consistent.
- 原材料使用是否按照要求? 原料标签信息是否记录完整;
Check that raw materials are used as requested? The material information on the label is complete.
- 确认机台上(机台附近) 清场是否彻底, 是否有上款产品或物料标签, 标签信息是否正确;
Check that line clearance is complete, there are any previous products or their labels, and information on the label is correct.
- 确认机台及自动化SS情况是否符合生产要求;
Check that SS of machine and automatic meet the requirements of production.

备注: 首件开机条件作业标准确认合格打“√”, 不合格打“✗”
Note: Operation standard for first article start-up conditions..qualified“√”, failed“✗”

开机条件不符合说明 Boot conditions are not specified.

 BOOMINGSHING MEDICAL 浙江柏明胜医疗科技有限公司 Zhejiang Boomingshing Medical Technology Co.,Ltd.						文件名称 Doc. Name	过程检查记录表 Process Inspection Record Form				版本 Version	01	发布日期 Published on	2023年YY10月 MM23日DD
						文件类型 DOC.Type	质量记录 Quality Record	文件编号 Doc.No.	ZB-QR-12051	页码 Page	1/1	实施日期 Executed on	2023年YY10月 MM24日DD	
机台号 Machine No: ZB-K-31-002		生产命令单 Job No: ZBS 0602-23120013		品名 Name: Assay-cup		产品日期章 Date Seal: N/A		产品阶段 Product phase: OQ□ PQ1□ PQ2□ MP量产口						
模具编号 Mould No: CH2022086D		批次号 Lot No: 2303908		模具穴数 Mold cavity: 1x64		原材料批次号 Raw material batch lots: B2-230230		OQ阶段 OQ.phase: 中值Nom□ 高值Max□ 低值Min□						
检查项目 Inspection item		白班/Day shift						夜班/Night shift						
		08:00-10:00	10:00-12:00	12:00-14:00	14:00-16:00	16:00-18:00	18:00-20:00	20:00-22:00	22:00-0:00	0:00-2:00	2:00-4:00	4:00-6:00	06:00-08:00	
机台巡检 按SIP、工程样板、限度板等 Machine inspection according to relevant Standard Inspection Procedure, Gold sample&limit board, etc	核对首件FAI check	OK	OK	OK	OK	OK	OK	OK						
	材料/颜色 Material/color	OK	OK	OK	OK	OK	OK	OK						
	外观检查 Appearance check	OK	OK	OK	OK	OK	OK	OK				N		
	条码标签检查 Barcode label check	N/A	N/A	N/A	N/A	N/A	N/A	N/A				A		
	包装袋/标签检查 Packing label check	N/A	N/A	N/A	N/A	N/A	N/A	N/A						
	包装检查 Packing check	OK	OK	OK	OK	OK	OK	OK						
	尺寸 Dimension	See attached dimension report												
巡检异常处理 Abnormal dispose:	结构/试装 Structure/assembly	OK	OK	OK	OK	OK	OK	OK				N		
	是否隔离或开异常单 Is product quarantined or deviation released?	N/A	N/A	N/A	N/A	N/A	N/A	N/A				A		
	生产负责人确认 Confirmation of production leader	N/A	N/A	N/A	N/A	N/A	N/A	N/A						
2H抽查结果 2H Sampling result:	2小时生产批数量 2H production QTY													
	IPQC抽样数量 IPQC sample size													
	抽查不良描述/数量 NC description /QTY											N		
	判定结果 Judgement result												A	
	不合格品处理方式 Disposal of NC products													
备注 Remark:	外观不良描述 Description of poor appearance: 色差Color deviation、缩水Shrinkage、缺胶Short shot、多胶Extra material、披锋/毛边Flash、变形Deform、夹水线/熔接痕Weld line、黑点Black point、混色Mixed color、烧焦Burned mark、气泡Bubble、裂痕Crack、压伤/划痕Scratch mark、困气air trapping、冷料发白White mark、油污Oil mark、胶位厚薄不均Uneven thickness、粘附异物Contaminated、雾面Matt mark、包装袋烂Bag damage、标签贴反Label stick on wrong direction、标签贴歪Label slant、漏贴标签Missing label、混料Mixed product、抛光不良Poor Polish、产品结构不符Structure deviation、段差/台阶 判定结果Judgement result: 合格/OK 退货/Reject 返工/Rework 让步接收/AOD 报废/Scrap													
	P02	N/A												
白班QC/日期 Day shift QC/Date:	王晓月 2023.12.30		审核/日期 Checked by/Date:	罗伟强 2023.12.30		夜班QC/日期 Night shift QC/Date:	秦龙颖 2023.12.30		审核/日期 Checked by/Date:	许主任 2023.12.30				
巡检标准: 外观: 1次/2H, 尺寸: 1啤/4H, 按照对应产品的SIP。如客户有要求则以客户要求为准。 Inspection standard: Appearance: once / 2H, size: 1short / 4H. According to the Quality Inspection Standards of the corresponding products. If the customer has any requirements, the customer shall prevail. 异常处理: IPQC 巡检发现品质异常, 第一次先口头通知生产班长或技术员进行改善, 在IPQC报告上确认签名, 2H后无改善效果的, IPQC则开出书面“品质异常联系单”。 If IPQC inspection finds abnormal quality, the production monitor or technician will be orally notified to improve the quality for the first time, and the IPQC will confirm the signature on the IPQC report. If there is no improvement effect after 2 hours, IPQC will issue a written "Contact Sheet for abnormal Quality". 保密密级: 敏感Confidentiality Level: Sensitive														