



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

日期: 2024.01.06

管代或管代授

权人

批准:

深圳市柏明胜医疗器械有限公司

生命命令

生产订单号	BMS0606-231200042	生产机台	L2G	模具尺寸
物料编码	B10500010002	厂内物料名称	L2G	制单日期
生产数量	4824	计量单位	盒	版本号
生产批号		水口/模		模具编号
计划公式(小时)	NaN	L报关数量		替代模具编号
颜色		周期(S)		物料规格
单重g		穴数		
外箱数量	36	内箱数量	0	副产品

完工产品入库记录

制单: 阎善红
审核: 阎善红
不收现金 (50000 k)
支票或电汇
日期: 2024-01-15

浙江柏明胜医疗科技有限公司

生之命令单

生产订单号	ZBS0602-231200010	生产机台		模具尺寸	
物料编码	B3250010005	厂内物料名称	Assay-tip	制单日期	2023-12-25
生产数量	506520	计量单位	件	版本号	
生产批号		水口/模		模具编号	CH2022087D
计划公式(小时)	10.33	上料夹数量		替代模具编号	
颜色		周期(S)	4.7	物料规格	黑色， φ6.0*18.0mm
单重g	0.257	穴数	61.00000	副产品	
外箱数量	0	内箱数量	0		
生产说明					
材料编码	材料名称	材料规格	子件	仓库	应领数量
13K0051 料盒)	Wasteliner F2G (F2G废	尺寸：145x114x418 mm,	采购		单位
B200010060	OPP PEEL OFF POLYBAG	外白色内套胶袋		402	可用量

审核：陶善红
四联红色（领原料） 五联绿色（领用单） ZB-QJR-32005

制单: 隋善红
一联白色(汗塑) 一联蓝色(存根)

浙江柏明胜医疗科技有限公司

生)
命令單

P62

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	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	CH202208510		
计划公式(小时)	9.11	L报关数量		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		66.7mm		
外箱数量	0	内箱数量	0	副产品			
生产说明							
材料编码	材料名称	材料规格	子件	仓库	应领数量	单位	可用量
13F0103	卷膜 (32MB600)	宽度：320mm, 厚度：0.032mm	采购		5	公斤	
B200130063	HIPS ALCOM MED PS 1000 AS141115 WT 1113-05	白色 WHITE	采购		467	公斤	

完工产品入库记录

制单:

审核：陶养红
四联红色（领固料） 五联绿色（领红料）

ZB-QR-32005

浙江柏明胜医疗科技有限公司

生江命令单

审核:陶善红
制单:陶善红
一联红色(领原料)
二联黄色(存根)
三联绿色(领色料)
四联白色(领原料)

生产订单号	ZBS0602-231200013	生产机台		模具尺寸	
物料编码	B3250010006	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	CHE20220861D
计划公式(小时)	10.11	上报关数量		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	副产品	
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 撕条	宽度：2mm；材质：PP	采购	1卷	
A200010047	TPP BORNEID™ R.J88030	透明 TRANSPARENT	采购	75公斤	

完工产品入库记录

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					PCS 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™ RJ880MO	透明 TRANSPARENT
ZBS0602-231200013	B32500010006	Assay-cup	13F0106	Red pull-thread 螺丝 NUT: PP	宽度: 2mm; 材 料: ROL
合计					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

72323
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：72*51, 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

机台Machine: ZB-K-31-0020 订单号Order No.: 31850602-2312000/6 品名Product No.: Assay - tip 模号Mold NO.: CH2022087D

日期 Date	班别 Shift	时间 Time	全程时间 (周期) Cycle	模具温度 Mold Temperatur		切换位置 Transfer Posi	残量位置 Melt Cushion	射出压力/速度 Injection Pressure/Speed					射出时间 Injection Time	冷却时间 Cooling Time	保压压力/时间 Holding Pressure/Time			炮筒温度 Barrel Temperature				调机状况记录 Debug Machine record	点检人 Checked by	QC确认 Confirm	主管确认 Reviewd By				
				前 Fixed	后 Movin			I1压力1 / IV1速度1	位置1	IP2压力2 / IV2速度2	位置2	IP3压力3 / IV3速度3	位置3		P1压力1 / T1时间1	P2压力2 / T2时间2	P3压力3 / T3时间3	H1 第一段	H2 第二段	H3 第三段	H4 第四段	HS 第五段	MAX	MIN					
2023 12.30	白 Day	08:00-14:00	5.4	58	30	35	15	14.83	900/50	38	900/40	20	900/50	15	0.275	1.2	450/23	/	/	245	245	235	225	200	240	240	N/A	柏明胜 马丽丽	中亮
		14:00-20:00		58	30	35	15	14.84	900/50	38	900/40	20	900/50	15	0.275	1.2	450/23	/	/	245	245	235	225	200	240	240	N/A	柏明胜 马丽丽	中亮
12.30	夜 Night	20:00-02:00	5.4	58	30	35	15	14.83	900/50	38	900/40	20	900/50	15	0.281	1.2	450/23	/	/	245	245	235	225	200	240	240	N/A	李锐峰 崔长新	中亮
		02:00-08:00																											
	白 Day	08:00-14:00																											
	夜 Night	20:00-02:00																											
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	夜 Night	02:00-08:00																											

确认内容说明 Confirmation Description	1、成型条件点检表与《成型工艺卡》一同使用并作为批记录文件归档。 1. The Moulding Setting Spot Check is in accord with Moulding Process Card and shall be filed as DHR. 2、点检表安实际参数填写，如超出《成型工艺卡》参数需提出部门主管确认。 2. Spot Check should be according to real parameters. If the parameter is exclude from the Molding Process Card, it should be confirmed by department manager.	P183
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机台Machine: ZB-1c-31-0022 订单号Order No.: ZBS002-231200012 品名Product No.: Assay-rack plain 模号Mold NO.: CL2022085D

日期 Date	班别 Shift	时间 Time	全程时间 (周期) Cycle	模具温度 Mold Temperatur		切换位置 Transfer Posi	残量位置 Melt Cushion	射出压力/速度 Injection Pressure/Speed					射出时间 Injection Time	冷却时间 Cooling Time	保压压力/时间 Holding Pressure/Time			炮筒温度 Barrel Temperature					调机状况记录 Debug Machine record	点检人 Checked by	QC确认 Confirm	主管确认 Reviewd By			
				前 Fixed	后 Movin			IPI压力1 /IV1速度1	位置1	IP2压力2 /IV2速度2	位置2	IP3压力3 /IV3速度3	位置3		P1压力1 /T1时间1	P2压力2 /T2时间2	P3压力3 /T3时间3	H1 第一段	H2 第二段	H3 第三段	H4 第四段	H5 第五段	MAX	MIN					
2023. 12.24	白 Day	08:00-14:00	16.1	20	45	113	5.5	5.03	110/80	110/200	50	1400/150	5.5	0.5	4.0	200/5	/	/	260	260	260	250	240	260	260	N/A	高亚丽	马丽娟	高亮
		14:00-20:00		20	45	113	5.5	5.04	110/80	110/200	50	1400/150	5.5	0.5	4.0	200/5	/	/	260	260	260	250	240	260	260	N/A	高亚丽	马丽娟	高亮
12.25	夜 Night	20:00-02:00	16.0	20	45	113	5.5	5.03	110/80	110/200	50	1400/150	5.5	0.5	4.0	200/5	/	/	260	260	260	250	240	260	260	N/A	王立龙	马丽娟	高亮
		02:00-08:00																											
	白 Day	08:00-14:00																											
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		02:00-08:00																											

确认内容说明
Confirmation
Description

- 1、成型条件点检表与《成型工艺卡》一同使用并作为批记录文件归档。
 1. The Moulding Setting Spot Check is in accord with Moulding Process Card and shall be filed as DHR.
 2. 点检表安实际参数填写, 如超出《成型工艺卡》参数需提出部门主管确认。
 2. Spot Check should be according to real parameters. If the parameter is exclude from the Molding Process Card, it should be confirmed by department manager.

P03

机台Machine: ZB-K-31-0021 订单号Order No.: 2BS0602-231200013

品名Product No: ABS cup

模号Mold NO: C112022086D

日期 Date	班别 Shift	时间 Time	全周期 Cycle	模具温度 Mold Temperature		计量 Dosing pos	切换位置 Transfer Posi	残量位置 Melt Cushion	射出压力/速度 Injection Pressure/Speed					射出时间 Injection Time	冷却时间 Cooling Time	保压压力/时间 Holding Pressure/Time			炮筒温度 Barrel Temperature					调机状况记录 Debug Machine record	点检人 Checked by	QC确认 Confirm	主管确认 Reviewd By			
				前 Fixed	后 Movin				IP1 压力1 / IV1 速度1	IP2 压力2 / IV2 速度2	位置1	IP3 压力3 / IV3 速度3	位置2	IP3 压力3 / IV3 速度3	位置3	P1 压力1 / T1 时间1	P2 压力2 / T2 时间2	P3 压力3 / T3 时间3	H1 第一段	H2 第二段	H3 第三段	H4 第四段	H5 第五段	MAX	MIN					
2023 12.30	白 Day	08:00-14:00	5.3	30	30	78	5	4.76	1000/50	73	1000/50	10	1000/50	5	0.46	1.0	60/0.2	/	/	240	240	230	220	200	250	240	N/A	王威	马丽	高亮
		14:00-20:00		30	30	78	5	4.76	1000/50	73	1000/50	10	1000/50	5	0.46	1.0	60/0.2	/	/	240	240	230	220	200	250	240	N/A	高强	马丽	高亮
12.30	夜 Night	20:00-02:00	5.3	30	30	78	5	4.75	1000/50	73	1000/50	10	1000/50	5	0.43	1.0	60/0.2	/	/	240	240	230	220	200	250	240	N/A	王云石	高强	高亮
		02:00-08:00																												
	白 Day	08:00-14:00																												
		14:00-20:00																												
	夜 Night	20:00-02:00																												
		02:00-08:00																												
	白 Day	08:00-14:00																												
		14:00-20:00																												
	夜 Night	20:00-02:00																												
		02:00-08:00																												
	白 Day	08:00-14:00																												
		14:00-20:00																												
	夜 Night	20:00-02:00																												
		02:00-08:00																												
	白 Day	08:00-14:00																												
		14:00-20:00																												
	夜 Night	20:00-02:00																												
		02:00-08:00																												
	白 Day	08:00-14:00																												
		14:00-20:00																												
	夜 Night	20:00-02:00																												
		02:00-08:00																												

确认内容说明 Confirmation Description 1、成型条件点检表与《成型工艺卡》一同使用并作为批记录文件归档。

1. The Moulding Setting Spot Check is in accord with Moulding Process Card and shall be filed as DHR.

2. 点检表安实际参数填写, 如超出《成型工艺卡》参数需提出部门主管确认。

2. Spot Check should be according to real parameters. If the parameter is exclude from the Molding Process Card, it should be confirmed by department manager.

P03

文件类型
Doc Type质量记录
Quality Record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.	20231220000000000000 Batch No.)	2023.12.20 DOE on label	2024.11.30 Order quantity	4804 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	申请人 (生产班长) Applicant	审批人 (主管级及以上) Approval by
第一次 No.1	V	821	N	126	陈书贤 Chen Shuxian	1234567890 Mold No.
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	821	N	V
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: 350602-271200012 批号: S27120006 质量记录Quality Record

成型作业时报表Production Process Hourly Tracking Report

模具编号: CJ202085D 2023年12月MM 24HDD 报 shift

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 Yield/hr	450Pcs.
报检数 N/A 箱CTN (袋Bag) * N/A = 896	上机尾数 Balance of off-shift	N/A	16"	1x2		

时 [h] Time	良品数 Accepted qtv	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: <input checked="" type="checkbox"/> OK <input type="checkbox"/> NG	判定结果 judgement result: <input checked="" type="checkbox"/> OK <input type="checkbox"/> NG	备注 Remark	
			黑点 black spot	气泡 bubble	划伤 Scratch	缩水 Shrinkage	鼓包穿孔 Bulge/tear	短屑 Short fiber								
08:00-09:00	180	机选 Machine sorted	0												0	After Setup
09:00-10:00	434	机选 Machine sorted	1												0	Initial Product
10:00-11:00	432	机选 Machine sorted	2												1	正常 Normal
11:00-12:00	430	机选 Machine sorted	0												0	正常 Normal
12:00-13:00	438	机选 Machine sorted	1												3	正常 Normal
13:00-14:00	372	机选 Machine sorted	0												0	正常 Normal
14:00-15:00	432	机选 Machine sorted	0												5	正常 Normal
15:00-16:00	440	机选 Machine sorted	1												0	正常 Normal
16:00-17:00	435	机选 Machine sorted	0												0	正常 Normal
17:00-18:00	345	机选 Machine sorted	0												0	正常 Normal
18:00-19:00	428	机选 Machine sorted	0												0	正常 Normal
19:00-20:00	426	机选 Machine sorted	1												0	正常 Normal
合计:			4792	N/A	6										16	N/A

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	启动机台, 检查并调整机器至正常生产状态。	启动 20min to the machine to the normal production status.	李继峰
09:00-10:00	Start up debugging, this piece confirmation.	Products that have been started up for 20 min directly scrapped.	N/A
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; 2.自动进料称重; 3.各部件处理; 4.零组件更换 (如增加风刀、放大板); 5.机器、自动化设备的停用、变更; 6.零件增加; 7.异常报警记录。Note: This record is for non-production work, including but not limited to: 1. Startup and initial adjustment of the machine; 2. Automatic feeding and weighing; 3. Various parts handling; 4. Component replacement (such as adding air fan or magnifier); 5. Machine shutdown; 6. Change or adding of equipment; 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.



13 MEDICAL

Yang Boomingshing Medical Technology C

版本号Version 01

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机号: 28-K-1-0022 生产订单号: 245062-23120002		批号: S23120006		Mould No.: CK1002085D	模具编号: CK1002085D	2023年12月24日班 Shift												
文件名:Doc Name		质量记录Quality Record		成型作业时报表Production Process Hourly Tracking Report														
客户 Customer	266	品名 Part name	String-wire Plan	周期 Cycle	16"	本班尾数 Balance of on-job shift												
检数 Inspect qty	142 箱/CTN (袋/Bag) * 1/4 = 288	上班尾数 Balance of off-shift	N/A	空数 Cavity	1x2	%量/Yield/Hr	45%											
时间 Time	良品数 QTY Accepted	类别 Category	不良品数 Defect: 0 PCS			不良率 Defect rate: 0 % (目标值 Target value: 5%)	判定结果 Judgement result: OK □ NG											
			外观不良 Cosmetic defects			撕裂线不 NG	包装膜不良 Packing film defects	标签不良 Label defects	备注 Remark									
			缺边/缺角 Scratch/cor	缩水 Shrinkage	缺胶穿孔 Expose	油污 Oil mark	异物 Foreign substance	毛刺/Burr/Fish	功能不良 Functional defects	漏气/漏油 Less attendance	印刷不良 Printing NG	偏移/offset >2mm	破损污染 Contamination	焊接不良 Welding is incomplete	污染损坏 Contaminant attached	粘连不牢 Not firmly attached	信息不良 Information NG	其他不良 Others
20:00-21:00	142	Manual sorted	人检	人检	人检													
21:00-22:00		Machine sorted	人检	人检	人检													
22:00-23:00		Manual sorted	人检	人检	人检													
23:00-24:00		Machine sorted	人检	人检	人检													
24:00-01:00		Manual sorted	人检	人检	人检													
01:00-02:00		Machine sorted	人检	人检	人检													
02:00-03:00		Manual sorted	人检	人检	人检													
03:00-04:00		Machine sorted	人检	人检	人检													
04:00-05:00		Manual sorted	人检	人检	人检													
05:00-06:00		Machine sorted	人检	人检	人检													
06:00-07:00		Manual sorted	人检	人检	人检													
07:00-08:00		Machine sorted	人检	人检	人检													
合计:	142																	
Total	142																	
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.																		
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			责任人签名 Ppl Signature											
20:00-21:00																		
21:00-22:00																		
22:00-23:00																		
23:00-24:00																		
24:00-01:00																		
01:00-02:00																		
02:00-03:00																		
03:00-04:00																		
04:00-05:00																		
05:00-06:00																		
06:00-07:00																		
07:00-08:00																		
总计:																		
Total																		
05:00-06:00																		
06:00-07:00																		
07:00-08:00																		
总计:																		
Total																		
07:00-08:00																		

Note: On-duty shifts must take over the balance quantity left by the off duty shifts

生产特殊活动记录表

机号: Machine#	2B-K-3-1-0022	生产订单号: Job order#	245002-23120002	批号: Lot No.	523120006	模具编号: Mould No.	C/H/20220851	成型作业时报表Production Process Hourly Tracking Report	
文件类型Doc Type	Zhejiang Boomingshing Medical Technology Co., Ltd.	文件编号Doc No.	ZB-QR-32037	版本号Version	01	页码Page	1/1	浙江柏明胜医疗科技有限公司	
客户Customer	266	品名Part name	Biang-Bak Hair	周用Cycle	16"	穴数Cavity	10	废量Waste	450/PCS

Note: On-duty shifts must take over the balance quantity left by the off duty shifts

07/000500
备注：此表仅适用于生产率的各种活动，包括但不限于以下所列：1.注塑机开机、调机、下模 2.自动线调整标签、换标签、调包装机等自动线调整 3.各种报警处理 4.改善措施执行（比如增加离于风箱、放大镜）5.计划、自动线设备的修理、变更、零部件增加 6.各种材料的常记录 7.若机器活动则恢复正常生产，并且N/A空白部分。三当生产不良率超过5%时，立即通知及进行停机改善。Note: This report records all activities happened outside normal production running, 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; Abnormal alarms handling; This report records all activities happened outside normal production running, 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; Abnormal alarms handling; 3. Report records all activities happened outside normal production running, 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; Abnormal alarms handling; 4. Line improvement (such as adding fan or magnetizer); 5. Repairing, change or adding of equipment; 6. Machine abnormal shutdown; 7. 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Mould No.

2023

年

月

日

班次Shift

机号: Machine#		生产订单号: Job order#		批号: Lot No.		成型作业时报表Production Process Hourly Tracking Report	
文件名称Doc Name							
% ²	Customer	15	品名: Part name	PSYNG-RANK STEAK	周用Cycle	55"	产出量/H Yield/hr
报检数: Inspect qty		箱CTN (袋Bag) × 1 = 150	上班尾数: Balance of off. shift	N/A	本班尾数: Balance of on-job shift	N/A	待处理数: To be dispose qty N/A

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 Packaging film defects	标签不良 Label defects	其他不良 Others	备注 Remark	
			黑点 black spot	气泡 bubble	划伤/碰伤 Scratch/Impact	缩水 Shrinkage	破洞穿孔 Hole	油污 Oil mark							
08:00-09:00	N/A	人选 Manual sorted													
09:00-10:00	31	机选 Machine sorted							1						
10:00-11:00	63	人选 Manual sorted													
11:00-12:00	64	机选 Machine sorted													
12:00-13:00	45	人选 Manual sorted													
13:00-14:00	65	机选 Machine sorted													
14:00-15:00	64	人选 Manual sorted													
15:00-16:00	63	机选 Machine sorted													
16:00-17:00	64	人选 Manual sorted													
17:00-18:00	48	机选 Machine sorted													
18:00-19:00	64	人选 Manual sorted													
19:00-20:00	64	机选 Machine sorted													
合计: Total	625	人选 Manual sorted													

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 Cause of the problem	处理方法 Disposing methods	责任人签名 Person Signature
08:00-09:00			
09:00-10:00			
10:00-11:00	Start up. Test & Check. first piece confirmation	Product info to 20mm from the edge. N/A	
11:00-12:00			
12:00-13:00			
13:00-14:00			
14:00-15:00			
15:00-16:00			
16:00-17:00			
17:00-18:00			
18:00-19:00	Mold maintenance	Clean the mold surface with a dust free cloth. N/A	
19:00-20:00			

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、风机、注塑机等) 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(白处部分: 当生产出现异常情况时, 请如实填写, 例如: 1.注塑机超温停机; 2.自动线技术员到岗; 3.异常报警发生; 4.注塑机故障; 5.注塑机停机; 6.各种设备故障; 7.无异常情况, 并且 N/A 在空白处) Note: This report records all activities happened outside normal production running, 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:

Published on 2023 4/YY 10 | MM 26 | DD 发布

Executed on 2023 4/YY 10 | MM 26 | DD 实施

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

机号: Machine No.

Line 29 生产订单号: Job order#

Batch No. 23001908

文件编号Doc No.

版本号Version

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Customer	品名 Part name	平衡尾数 Balance of off-shift	周用 Cycle	空缺 Cavity	本班尾数 Balance of on-job shift	Yield/Hr	Yield/Hr	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	备注 Remark
Inspect QTY	箱CTN (袋Bag) × 1 = 5Pcs										

时间 Time	良品数 Accepted qty	类别 Category	外观不良 Cosmetic defects	功能不良 Functional defects	撕裂线不直 Tear line	包装膜不良 Packing film defects	标签不良 Label defects	其他不良 Others
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	缺胶穿孔 Short shoot	油污 Oil mark
21:00-22:00	65	人选 Manual sorted	人选 Manual sorted	机选 Machine sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted
22:00-23:00	40	机选 Machine sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted
23:00-24:00		机选 Machine sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted
24:00-01:00		人选 Manual sorted	机选 Machine sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted
01:00-02:00		人选 Manual sorted	机选 Machine sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted
02:00-03:00		人选 Manual sorted	机选 Machine sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted
03:00-04:00		人选 Manual sorted	机选 Machine sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted
04:00-05:00		人选 Manual sorted	机选 Machine sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted
05:00-06:00		人选 Manual sorted	机选 Machine sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted
06:00-07:00		人选 Manual sorted	机选 Machine sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted
07:00-08:00		人选 Manual sorted	机选 Machine sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted	人选 Manual sorted
Total	170							

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.

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

Disposing methods

责任人签名 Pp Signature

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; 调色装机等自动线调机调整; 3.各种报警处理; 4.改善措施执行 (比如增加滤网/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“待机”或“停止”状态; 6.正常生产过程中发生的异常情况; 7.当生产缺陷率超过5%时, 技术人员应及时通知并立即停止生产。此报告记录所有活动, 包括但不限于: 1.注塑机停机、调机; 2.自动线调整标签、换标签; 调色装机等自动线调机调整; 3.各种报警处理; 4.改善措施执行 (比如增加滤网/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“待机”或“停止”状态; 6.正常生产过程中发生的异常情况; 7.当生产缺陷率超过5%时, 技术人员应及时通知并立即停止生产。

作业员Operator: 王伟军 2023.12.30 班长Prod.leader/技师Technician: 夏敏军 2023.12.30 演练QC leader/经理Manager: 夏敏军 2023.12.30 密密级: 敏感Confidentiality Level: Sensitive

文件类型 Document Type	质量记录 Quality Record
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标题 Title

E2G 外包装检查记录表

Ne7

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

名称 Name	检查内容 Inspection Details	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	18: 00-20: 00	20: 00-22: 00	22: 00-24: 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"/>	<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"/>	<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"/>	<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"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	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"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
堆垛 Stacking	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"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	未按 $4 \times 3 = 12$ 箱/棧板堆放 (4 张防滑纸) Not stacked according to $4 \times 3 = 12$ 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"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
外观 Appearance	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"/>	<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"/>	<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%	0.7%	0.7%	0.7%	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 例 号 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

品名 Name:

Assay tip/Assay cup tray

机台 Machine:

Line 29

生产命令单 Job No:

Assy_d02-23120004P

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 Product barcode	班长	<i>N/A</i>		
2	内袋标签 Inner box label	班长	<input checked="" type="checkbox"/>		
3	SOP	班长	<input checked="" type="checkbox"/>		
4	包装指导书 Packing SOP	班长	<input checked="" type="checkbox"/>		
5	品质文件/SIP Quality Document	班长	<input checked="" type="checkbox"/>		
6	包材 Package material	班长	<input checked="" type="checkbox"/>		
7	人员安排 Arrangement of people	班长	<input checked="" type="checkbox"/>		
8	工作台清理 Cleaning of worktable	作业员	<input checked="" type="checkbox"/>		
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	<input checked="" type="checkbox"/>		

注: Ok 写“√”, 不适用写“N/A”

保密密级: 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



浙江铂明生医疗科技有限公司
Zhejiang Bomingsheng Medical Technology Co., Ltd

ZHEJIANG BONMINGSHENG MEDICAL TECHNOLOGY CO., LTD.	浙江博明生医疗科技有限公司	文件编号 Doc No.	ZB-QR-52010
		版本号 Version	00
文件类型 Document Type	质量记录 Quality Record	页码 Page	1 / 1
标题 Title	入库单 Inbound Form		

仓库 Warehouse: 保税成品仓

入库单号 Warehousing order number: Z

order number

4010003

1

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
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134

Amount to	4824	4824
合計		

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

审核人 Auditor: 王江 2024.01.06

 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: 2023.10.21 送检人Person for inspection: 张燕 日期Date: 2023.10.21				AssayTip/AssayCup tray Roche			1. 生产日期 (标签上): Production date: _____ N/A	0/C	_____	_____	
				AssayTip/AssayCup tray Roche			2. 有效期长: Period of validity: _____ 23个月	0/C	2023.10	_____	
							3. 失效日期: Expired date: _____ 2025.11.30	0/C	2025.11.30	_____	
							4. 打印清晰/无断线/无脏污 Clear and legible/no short ink and dirt OK	0/C	2025.11.30	_____	
<p>Inner box label</p> <p>AssayTip/AssayCup tray </p> <p> REF 05694302001 LOT 23003908 2025-11-30</p> <p>+2°C CONTENT 6 CE IVD dialog.roche.com</p> <p>cobas®</p> <p>AssayTip/AssayCup tray </p> <p> REF 05694302001 LOT 23003908 2025-11-30</p> <p>+2°C CONTENT 6 CE IVD dialog.roche.com</p> <p>cobas®</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。

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(11)23224(17)251130(20)05694302001</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		
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Omron Microscan Systems, Inc. LVS-95xx Verification Report

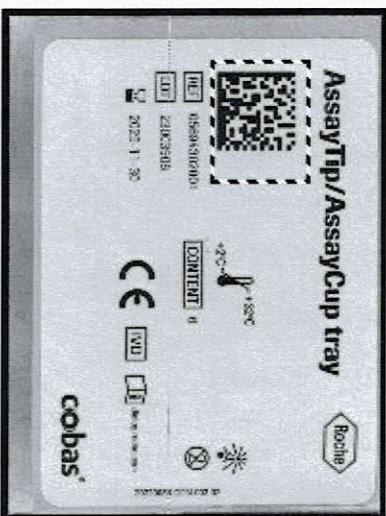
P63

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

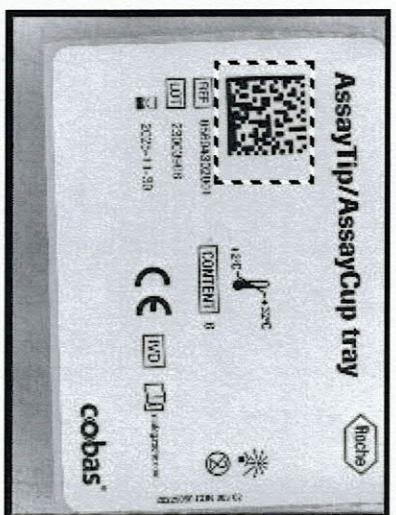
Reference: admin

王 晓月 2023.12.29

Operator signature

王 晓月 2023.12.29

Second signature



2D		Other information	
Symbology	GS1 Data Matrix	GS1 Data	(1)023003908(17251130(240)056
Decoded text	102300390817251130240056943020	GS1 Data Structure	94302001
Cell size	01	Pass/Fail	PASS
Decode	26.5 mils	Letter Grade	A
Contrast	PASS	ReportID	3786
Modulation	4.0 85%	Operator	admin (LVS Administrator)
Reflectance margin	4.0	Application standard	GS1 General Specifications
Axial nonuniformity	4.0 0.5%	GS1 Table	Table 1 - Trade Items Scanned in General Retail POS and not General Distribution
Grid nonuniformity	4.0 7%	Limit Action	Change grade to F if Xdim or symbol height is outside limits
Unused EC	4.0 100%	Effective aperture	Reference number 08 (7.95 mil)
Fixed pattern damage	4.0	Lighting	660/D
L1 (left of L finder)	4.0	Date and time	29-Dec-2023 14:35 local; 29-Dec-2023 06:35 GMT
L2 (bottom of L finder)	4.0	Time zone	GMT +8
QZL1 (left quiet zone)	4.0	Sector size	0.71" by 0.58"
QZL2 (bottom quiet zone)	4.0	Last calibration	11-Dec-2023 10:26 local; 11-Dec-2023 02:26 GMT
CTR (clock track regularity)	4.0	Field of view	3.03" (camera is 2592x1944 pixels)
CTID (clock track damage)	4.0	Serial numbers	Unit: 2248426, Camera: 1222024
SFP (solid fixed pattern)	4.0	Software product and version	4, Model: 9580
OCTASA (overall clock track and solid area)	4.0	LVS-95xx Version 4.4.3.4102	
AG (average grade)	4.0	Manufactured by:	Omron Microscan Systems, Inc.
TR (transition ratio)	4.0 0.00		700 SW 39th Street, Ste. 100 Renton, WA 98057 USA
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		

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 done“/”, 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	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	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	黄威	黄威	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	首件尺寸见 表See the first size report for measured dimensions	ok	ok	N/A	ok	N/A	N/A	ok	王晓月	王晓月	2023.12.24
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

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 (全自动脱模机/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.
- 原料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“✗”; failed “✗”

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:		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:						
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	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 for measured dimensions	OK	OK	N/A	N/A	N/A	OK	OK	王海	王海	09:30	
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 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“✗”, 失格打“✗” 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												
保密等级: 机密Confidentiality Level: Executed on 2023年10月MM 24日DD 实施												

上海三思电子有限公司 Shanghai Suntronics 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
文件类型 Doc. Type	质量记录 Quality Record	文件编号 Doc. No.	ZS-QR-12071	页码 Page

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

日期 Date,	2023.12.30	生产命令单 Job No.	2850b02-231200010	批次号 Lot No.	24003908
机台号 Machine No.	2B-K-31-0020	模具编号 Mould No.	CH2022087D	品名 product name:	Assy-EPP
原材料名称 Material	PP PRE-ELEC TR 1000	原材料批次号 Raw material batch no:	90665	产品日期章 Date Seal:	N/A

末件检查 Final piece inspection

试产模具首件 The first mold in trial production

P03

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	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 Confirmor	送检时间 Inspection Time
第一次 First Time	OK	OK	N/A	N/A	OK	无法判断 无法判断	N/A	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

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	修模后效果确认 Confirm the effect after mold repair.
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
第二次 Second Time			N
第三次 Third Time			A

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

分析人/日期 Analyze the person/date:

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.

- 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 SPC 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.
- 确认机台及自动化情况是否符合生产需求?
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 the machine area (near the machine) is clean and there are no previous products or their labels, and information on the label is correct.

N
A

- 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 “✗”.
- 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 “✗”.

开机条件不复合说明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)
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



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-K31-0020

模具编号
Mould No: CH2022087D

检查项目
Inspection item

按SIP、工程样板、限度板等
Machine inspection according to relevant Standard Inspection Procedure, Gold sample&limit board, etc

巡检异常处理
Abnormal dispose:

2H抽查结果
2H Sampling result:

备注
Remark:

白班QC/日期
Day shift QC/Date:

夜班QC/日期
Night shift QC/Date:

审核/日期
Checked by/Date:

白班QC/日期
Day shift QC/Date:

夜班QC/日期
Night shift QC/Date:

审核/日期
Checked by/Date:

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: 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

生产命令单
Job No: ZBS0602-231200010

批次号
Lot No: 23003908

时间/Time

品名
Name: Assay-tip

模具穴数
Mold cavity: 1x64

产品日期章
Date Seal: N/A

原材料批次号
Raw material batch lots: 90665

产品阶段
Product phase: OQ□ PQ1□ PQ2□ MP量产口

OQ阶段
OQ phase: 中值Nom□ 高值Max□ 低值Min□

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	6:00-8:00
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OK											
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OK											
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OK											
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N/A											
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N/A											
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OK											
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尺寸 Dimension	See attached dimension report										
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OK											
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N/A											
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N/A											
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2小时生产批量数 2H production QTY											
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IPQC抽样数量 IPQC sample size											
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抽查不良描述/数量 NC description /QTY											
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判定结果 Judgement result											
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不合格品处理方式 Disposal of NC products											
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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Step difference

判定结果 Judgement result: 合格/OK 退货/Reject 返工/Rework 让步接收/AOD 报废/Scrap

P03 N/A

王晓月

2023.12.30

审核/日期
Checked by/Date:

王晓月

2023.12.30

审核/日期
Checked by/Date:

王晓月

审核/日期
Checked by/Date:

2023.12.30

文件名称	产品首/末件确认单		
Doc. Name	Product First/Last Piece Confirmation		
文件类型	质量记录	文件编号	版本
Doc. Type	Quality Record	Doc. No.	01
日期 Date,	2023/12/30	生产命令单 Job No:	2850002-23200013
机台号 Machine No.,	2B-K-31-002	模具编号 Mould No.:	C12022086D
原材料名称 Material	PP BORNED™ R7800W	原材料批次号 Raw material batch no.:	B2-230230
批次数号 Lot No.: 2303908			
品名 product name: Assay-Cup			
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
第一次First Time	OK	OK	N/A
第二次Second Time			N/A
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	修模问题点 Repair mold problem point
第一次 First Time	首件尺寸报表 See the first size report for measured dimensions	OK	OK
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	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 certificate 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要求: Check that 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 “✗”		技术员 Technican: 肖生伟	IPOC 王成月
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12月23日 00:00 发布			
保密密级: 敏感 Confidentiality Level: Executed on 2023年12月23日 00:00 实施			

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.:	2B5D62-23120003	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

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	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														

浙江海康威视数字技术有限公司 Zhejiang Hikvision Digital Technology Co., Ltd.	文件名称 Doc. Name	产品首/末件确认单 Product First/Last Piece Confirmation	版本 Version	0.1
文件类型 Doc. Type	质量记录 Quality Record	文件编号 Doc. No.	ZB-QR-12071	页码 Page
<input checked="" type="checkbox"/> 首件检查 First piece inspection			<input checked="" type="checkbox"/> 末件检查 Final piece inspection	
<input type="checkbox"/> 维修后首件 The first piece after mold repair			<input type="checkbox"/> 试产模具首件 The first mold in trial production	
日期 Date:	2023.12.30	生产命令单 Job No:	BMS0606-21200042	批次号 Lot No.: B0278
机台号 Machine No.:	ZB-K3-002/2B-1C-3/ 020	模具编号 Mould No.:	4102220860/CH2022087D	品名 product name: <u>塑壳-HDPE-EPE-TPU</u>
原材料名称 Material	POLY(ENE) TPU PP/PE-EPE-TPU	原材料批次号 Raw material batch no.:	b2-23020/90665	产品日期章 Date Seal: <u>2023.12</u>
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
第一次First Time	OK	OK	N/A	N/A
第二次Second Time				
第三次Third Time				
不符合项原因分析 Cause analysis of nonconformance item:				
N/A				
不符合项改善对策 Improvement measures for nonconformance items:				
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		技术人员确认 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 certified or acquainted with products.				
2.无注塑参数卡、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, 机模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、机台上实际参数与成型工艺卡三者是否一致; Check that 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? 原材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) 清洁度是否彻底, 是否有上一款产品或物料标签, 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“√”, 不合格打“✗”, 失败打“✗” 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) Sensitive Published on 2023年12月23日 00:00				

客户名称: 宁波市新嘉隆模具有限公司 Machine No.: 2B-K-3-002 原材料名称: PP42M70D7800 Material: PA66-GF30-ELEC-TPU65		文件名称: Product First/Last Piece Confirmation Doc. Name: Product First/Last Piece Confirmation 文件类型: Quality Record Doc. Type: Quality Record	产品首/末件确认单 Product First/Last Piece Confirmation 文件编号: ZG-QR-12071 Doc. No.: ZG-QR-12071 版本: 01 Page: 1/1					
		P03						
<p><input type="checkbox"/> 首件检查 First piece inspection <input type="checkbox"/> 修模后首件 The first piece after mold repair</p> <p><input checked="" type="checkbox"/> 末件检查 Final piece inspection <input type="checkbox"/> 试产模具首件 The first mold in trial production</p>								
日期 Date:	2023.12.30	生产命令单 Job No.:	PMS0606-231200042 批次数号 Lot No.:					
机台号 Machine No.:	2B-K-3-002	模具编号 Mould No.:	CH20220860 / CH2022087D 品名 product name:					
原材料批次号 Raw material batch no.:	Bi-230230 / 90665 产品日期章 Date Seal:	页码 Page:	2023.12					
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	送检人 Inspector	初判人 Primary Confirmor	送检时间 Inspection Time
第一次 First Time	OK							2023.12.30 22:18
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	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
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	N/A	OK	OK	2023.12.30 22:40
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								
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				技术人员确认 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.有无注塑参数卡、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; 机器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 the 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SS情况是否符合生产要求; Check that the machine and automatic meet the requirements of production.								
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) Sensitive Published on 2023年12月23日 00 发布								
保密等级: 敏感 Confidentiality Level: Executed on 2023年12月24日 00 实施								



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 ZB-K-3-0021
Machine No: ZB-K-3-0020

模具编号 CH2022 086D CH2022 087D
Mould No:

生产命令单 Job No: BMS0606-231200042

批次号 Lot No: 2303908

品名 Name: Assay-rack-Satck

模具穴数 Mold cavity: N/A

产品日期章 Date Seal:

2023.12

原材料批次号 Raw material batch lots:

B2-230230
90665

产品阶段 Product phase:

OQ□ PQ1□ PQ2□ MP量产口

OQ阶段 OQ phase:

中值Nom□ 高值Max□ 低值Min□

时间/Time

白班/Day shift

夜班/Night shift

检查项目
Inspection item

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	6:00-08:00
-------------	-------------	-------------	-------------	-------------	-------------	-------------	------------	-----------	-----------	-----------	------------

机台巡检
按SIP、工程样板、限度板等
Machine inspection acording to relevant Standard Inspection Procedure ,Gold sample&limit board, etc

核对首件FAI check

OK											
----	----	----	----	----	----	----	----	----	----	----	--

材料/颜色 Material/color

OK											
----	----	----	----	----	----	----	----	----	----	----	--

外观检查 Appearance check

OK	N										
----	----	----	----	----	----	----	----	----	----	---	--

条码标签检查 Barcode label check

N/A	R										
-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	---	--

包装袋/标签检查 Packing label check

OK											
----	----	----	----	----	----	----	----	----	----	--	--

包装检查 Packing check

OK											
----	----	----	----	----	----	----	----	----	----	--	--

尺寸 Dimension

See attached dimension report

结构/试装 Structure/assembly

OK											
----	----	----	----	----	----	----	----	----	----	--	--

巡检异常处理
Abnormal dispose:

是否隔离或开异常单 Is product quarantined or deviation released?

N/A											
-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	--	--

生产负责人确认 Confirmation of production leader

N/A											
-----	-----	-----	-----	-----	-----	-----	-----	-----	-----	--	--

2H抽查结果
2H Sampling result:

2小时生产批量数 2H prodution QTY

31	127	110	127	112	128	130	40				
----	-----	-----	-----	-----	-----	-----	----	--	--	--	--

IPQC抽样数量 IPQC sample size

8	20	20	20	20	20	20	8				
---	----	----	----	----	----	----	---	--	--	--	--

抽查不良描述/数量 NC description /QTY

0	0	0	0	0	0	0	0				
---	---	---	---	---	---	---	---	--	--	--	--

判定结果 Judgement result

OK											
----	----	----	----	----	----	----	----	--	--	--	--

不合格品处理方式 Disposal of NC products

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、因气孔 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

P63 N/A

白班QC/日期
Day shift QC/Date:

王晓月 2023.12.30

审核/日期
Checked by/Date:

2023.12.30

夜班QC/日期
Night shift QC/Date:

麦龙颖 2023.12.30

审核/日期
Checked by/Date:

许玉 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

P023

		QA抽检表				版本	00	
		文件名称 Doc. Name	QA Sampling Inspection Record	文件类型 Doc. Type	质量记录 Quality Record	文件编号 Doc. No.	页码 Page	1/1
品名 Part name	Assy Tip/Assy cup tray	品号 Part	0569430201	批号 LOT No.	2303908	检查日期 Inspect Date	2024/01/02	
报验总数量 Total Qty.	134	抽样数 Sample Size	20	Ac	0	Re	1	
抽样标准Sampling Standard ISO2859-1	级 AQL 0.65	检验项目 Inspection Items	检验结果 Inspection Result				判定 OK/NG	
1	包装箱外观 (内盒、外箱) Shipper box)	<input checked="" type="checkbox"/> 符合 Good <input type="checkbox"/> 不符合 NG 1.型号、规格正确无误; Model/spec. is correct; 2.包装箱无破损、脏污等不良; package no damage, no dirty; 3.箱体印刷字体、颜色、图案等內容清晰、正确、无误。 Printing font, color, pattern are clear, correct and without error.				OK		
2	产品包装 Product Package	数量 Quantity	(6) PCS/包	(6) 包/内箱	内箱/外箱 inner box/carton	36 pcs/箱 pcsc/carton	OK	
	方式 Package Method	<input checked="" type="checkbox"/> 符合 Good <input type="checkbox"/> 不符合 NG <input checked="" type="checkbox"/> 无 No <input type="checkbox"/> 有 Yes				OK		
	错装/混装 WrongMix	<input checked="" type="checkbox"/> 无 No <input type="checkbox"/> 有 Yes				OK		
	杂物/粉尘 DirtyDust	<input checked="" type="checkbox"/> 无 No <input type="checkbox"/> 有 Yes				OK		
	其他 Others	<input checked="" type="checkbox"/> 有 Yes <input type="checkbox"/> 无 No				OK		
3	内、外箱票 、证书 Label, Certificate	<input checked="" type="checkbox"/> 内容清晰/完整/正确 content clear / full / correct				OK		
4	产品外观 Product Cosmetic	<input checked="" type="checkbox"/> 材质、外观、颜色、规格 Material, Appearance, Color Material, Appearance, Color Spec.				OK		
	产品条码/标签是否翘起 barcode label tilted	<input checked="" type="checkbox"/> 无 No <input type="checkbox"/> 有 Yes				OK		
	异物/foreign matter	<input checked="" type="checkbox"/> 无 No <input type="checkbox"/> 有 Yes				OK		
	其他 Others	<input checked="" type="checkbox"/> 无 No <input type="checkbox"/> 有 Yes				OK		
5	产品尺寸 Dimension	规格 Spec	1	2	3	4	5	
6	产品性能 Function	1. 丝印、喷涂附着力、耐磨性测试 Printing, painting adhesion and resistance test 2. 推拉力测试 Push and Pull Test 3. 透光率检测 Optical Test 4. 密封泄露测试 Leak Test 5. 其它性能测试 Other Test				<input checked="" type="checkbox"/> 合格 Pass <input type="checkbox"/> 不合格 NG		
结果判定 Conclusion 备注 Comments: <i>N/A</i>								
检验员日期/Inspector Date <i>2024/01/02</i>				审核日期/Reviewer Date <i>2024/01/06</i>				

第一联质量 (白) 第二联生产/仓库 (红) 1st page for quality(white), 2nd page for production/warehouse(red)

说明 Notes: 1. 检验项目根据产品型号选择相对应的SIP等相关资料。Inspection item follow relative document, such as SIP.

2. 以上检验项目全部合格，才能判定此批合格。如有不良写明具体不良内容。Conclusion is pass for all inspection item are OK, or fill defective content.

3. 性能测试填写具体数据，如为外观或其他判定无具体数据时，则写“OK”或“NG”。Function test fill actual data, fill OK or NG for the appearance when no actual data available.

4. 尺寸、性能检查每批次抽3-Specs批次。Dimension, functional check 3-Specs for each lot.

PQ3 Report for E2G_Assay-rack plain



浙江柏明胜医疗科技有限公司
Zhejiang Boomingshing Medical Technology Co.,Ltd.

文件编号 Doc No.	ZB-QR-12075
版本号 Version	00

文件类型 Document Type		质量记录 / Quality Record		标题 Title	尺寸检测记录 / Dimensional Inspection Record			记录编号 Record No.:	CL23122001	页码 Page																							
顾客名称/编号 Customer Name/No.		Roche/266		产品名称 Project Name	Assay-rack plain		组件名称 Part Name	AssayTip/AssayCup tray			检验依据 Inspection basis	ZB-SIP-12009-A1 罗氏E2G托底尺寸检验规范附件 Annex to Roche E2G Dimension standard inspection specification of Assay-Rack plain				color	Tolerance																
图纸编号 Drawing No.		5690030001		图纸版本号 Drawing versions	0		生产线Product line	<input checked="" type="checkbox"/> E2_M_029 ~ E2_M_030			原料类型 Material Type	<input checked="" type="checkbox"/> 原料 Material 口水口料degraded material <input type="checkbox"/> ___% 原料Material+___% 口水口料degraded material				Green	below 50%																
模具编号 Mold No.		<input checked="" type="checkbox"/> CH20220085D <input type="checkbox"/> CH20220254D		抽样日期/时间 Sampling Date/Time	2023.12.24		批号Lot	S23120006			阶段 stage	<input type="checkbox"/> 试模Test mould <input type="checkbox"/> 验证qualification <input checked="" type="checkbox"/> 正常生产 nominal <input type="checkbox"/> 其他others				Yellow	50%~80%																
抽样水平 Level of sampling		ISO2859 S4		抽样数量 Sampling Quality	2.5模/次 2.5shots/time (Middle)		接收标准 AQL	AQL=0.15; AC/RE=0/1			单位 Unit	mm				Dark Yellow	80%~100%																
测试结果Measured dimensions/复测结果double Measured dimensions														Red	above 100%																		
检测时间 Inspecti on Time	Dimension (info from drawing)			Tolerances			首件 08:00-12:00			AVERAGE	Deviation*	Used tol.%*	Result	巡检 12:00-16:00			AVERAGE	Deviation*	Used tol.%*	Result	巡检 16:00-20:00			AVERAGE	Deviation*	Used tol.%*	Result	测量设备 measuring equipment					
	球标	图区	Nominal*	+	-	JH01_1	JH01_2	JH02_1	JH02-2	JH02_3	JH01_1	JH01-2	JH01_3	JH02_1	JH02_2	JH01_1	JH01_2	JH02_1	JH02_2	JH02_3	JH01_1	JH01_2	JH02_1	JH02_2	JH02_3	JH01_1	JH01_2	JH02_1	JH02_2	JH02_3			
	48 H	①-1	A11	25.9	0.1	0.1	25.870	25.873	25.894	25.883	25.874	25.879	-0.021	21.4%	OK	25.895	25.889	25.895	25.884	25.889	25.891	-0.010	9.5%	OK	25.891	25.888	25.887	25.900	25.894	25.892	-0.008	7.8%	OK
48 H	①-2	A11	25.9	0.1	0.1	25.893	25.895	25.906	25.890	25.880	25.893	-0.007	7.0%	OK	25.908	25.905	25.910	25.890	25.897	25.902	0.002	2.0%	OK	25.906	25.907	25.888	25.902	25.893	25.899	-0.001	0.8%	OK	HD
48 H	①-3	A11	25.9	0.1	0.1	25.889	25.891	25.908	25.888	25.875	25.890	-0.010	9.6%	OK	25.895	25.897	25.900	25.882	25.888	25.893	-0.007	7.4%	OK	25.899	25.901	25.884	25.894	25.887	25.893	-0.007	7.0%	OK	HD
48 H	①-4	A11	25.9	0.1	0.1	25.904	25.902	25.921	25.895	25.881	25.900	0.000	0.5%	OK	25.902	25.902	25.905	25.891	25.890	25.904	-0.001	1.2%	OK	25.908	25.909	25.893	25.901	25.897	25.901	-0.001	1.3%	OK	HD
48 H	①-5	A11	25.9	0.1	0.1	25.916	25.910	25.929	25.907	25.905	25.913	0.013	13.1%	OK	25.911	25.912	25.918	25.904	25.924	25.914	0.014	13.6%	OK	25.912	25.920	25.902	25.914	25.917	25.913	-0.013	13.1%	OK	HD
48 H	①-6	A11	25.9	0.1	0.1	25.982	25.984	25.982	25.947	25.961	25.971	0.071	71.0%	OK	25.982	25.981	25.989	25.969	25.965	25.977	0.077	77.3%	OK	25.956	25.976	25.949	25.968	25.977	25.965	-0.065	65.3%	OK	HD
48 H	①-7	A11	25.9	0.1	0.1	25.934	25.933	25.937	25.929	25.923	25.931	0.031	31.2%	OK	25.928	25.922	25.933	25.925	25.928	25.927	0.028	28.2%	OK	25.913	25.920	25.913	25.933	25.915	25.919	-0.019	18.8%	OK	HD
48 H	①-8	A11	25.9	0.1	0.1	25.975	25.971	25.952	25.947	25.945	25.958	0.058	58.4%	OK	25.969	25.976	25.985	25.947	25.950	25.966	0.066	65.5%	OK	25.949	25.957	25.929	25.951	25.936	25.944	-0.044	44.5%	OK	HD
48 H	①-9	A11	25.9	0.1	0.1	25.930	25.928	25.947	25.943	25.950	25.940	0.040	39.8%	OK	25.932	25.938	25.957	25.960	25.948	25.947	0.047	47.1%	OK	25.938	25.929	25.926	25.957	25.937	25.937	-0.037	37.4%	OK	HD
48 H	①-10	A11	25.9	0.1	0.1	25.918	25.925	25.933	25.945	25.931	25.931	0.031	31.3%	OK	25.937	25.922	25.929	25.953	25.940	25.936	0.036	36.3%	OK	25.921	25.927	25.920	25.951	25.933	25.930	-0.030	30.2%	OK	HD
48 H	①-11	A11	25.9	0.1	0.1	25.894	25.900	25.911	25.916	25.918	25.908	0.008	7.6%	OK	25.898	25.892	25.903	25.922	25.914	25.906	0.006	5.6%	OK	25.894	25.901	25.900	25.919	25.904	25.904	-0.004	4.3%	OK	HD
48 H	①-12	A11	25.9	0.1	0.1	25.895	25.896	25.899	25.895	25.897	25.897	-0.003	2.9%	OK	25.891	25.891	25.898	25.908	25.897	25.899	-0.001	1.3%	OK	25.884	25.891	25.887	25.903	25.894	25.892	-0.008	8.2%	OK	HD
48 H	①-13	A11	25.9	0.1	0.1	25.894	25.898	25.892	25.892	25.894	25.894	-0.006	5.6%	OK	25.895	25.887	25.900	25.902	25.896	25.896	-0.004	3.9%	OK	25.897	25.902	25.891	25.905	25.902	25.899	-0.001	0.7%	OK	HD
48 H	①-14	A11	25.9	0.1	0.1	25.949	25.930	25.893	25.888	25.883	25.908	0.009	8.5%	OK	25.920	25.951	25.949	25.894	25.885	25.920	0.020	19.8%	OK	25.931	25.932	25.888	25.900	25.910	25.910	-0.010	9.5%	OK	HD
48 H	①-15	A11	25.9	0.1	0.1	25.889	25.895	25.914	25.894	25.883	25.896	-0.004	4.2%	OK	25.901	25.901	25.902	25.867	25.908	25.902	0.002	1.6%	OK	25.907	25.908	25.891	25.904	25.902	25.902	-0.002	2.2%	OK	HD
48 H	①-16	A11	25.9	0.1	0.1	25.894	25.896	25.906	25.893	25.873	25.892	-0.008	7.7%	OK	25.914	25.900	25.902	25.887	25.899	25.900	0.000	0.3%	OK	25.903	25.906	25.884	25.897	25.895	25.895	-0.005	4.7%	OK	HD
48 H	①-17	A11	25.9	0.1	0.1	25.889	25.895	25.911	25.895	25.876	25.893	-0.007	6.8%	OK	25.905	25.903	25.894	25.888	25.897	25.897	-0.003	2.5%	OK	25.913	25.908	25.884	25.900	25.900	25.900	-0.000	0.4%	OK	HD
48 H	①-18	A11	25.9	0.1	0.1	25.868	25.866	25.887	25.874	25.862	25.871	-0.029	28.6%	OK	25.875	25.896	25.886	25.876	25.880	25.883	-0.017	17.3%	OK	25.889	25.880	25.870	25.890	25.884	25.885	-0.015	15.3%	OK	HD
48 H	②-1	A11	25.5	0.1	0.1	25.488	25.485	25.469	25.489	25.481	25.482	-0.018	18.1%	OK	25.476	25.487	25.483	25.466	25.490	25.480	-0.020	19.7%	OK	25.486	25.478	25.475	25.469	25.477	25.477	-0.023	22.9%	OK	HD
48 H	②-2	A11	25.5	0.1	0.1	25.483	25.481	25.477	25.497	25.488	25.485	-0.015	14.8%	OK	25.474	25.484	25.480	25.474	25.497	25.482	-0.018	18.2%	OK	25.484	25.476	25.481	25.475	25.485	25.480	-0.020	19.9%	OK	HD
48 H	②-3	A11	25.5	0.1	0.1	25.464	25.462	25.482	25.496	25.481	25.477	-0.023	23.2%	OK	25.460	25.471	25.465	25.495	25.504	25.479	-0.021	21.1%	OK	25.468	25.462	25.480	25.482	25.477	25.477	-0.023	22.9%	OK	HD
48 H	②-4	A11	25.5	0.1	0.1	25.466	25.463	25.475	25.474	25.474	25.474	-0.026	26.2%	OK	25.462	25.473	25.467	25.472	25.519	25.518	-0.022	21.5%	OK	25.469	25.464	25.475	25.475	25.475	25.475	-0.025	25.2%	OK	HD
48 H	②-5	A11	25.5	0.1	0.1	25.481	25.476	25.508	25.534	25.521	25.504	-0.004	3.8%	OK	25.476	25.479	25.480	25.538	25.546	25.503	-0.003	3.4%	OK	25.477	25.477	25.516	25.522	25.509	25.496	-0.004	3.8%	OK	HD
48 H	②-6	A11	25.5	0.1	0.1	25.459	25.456	25.483	25.503	25.495	25.479	-0.021	20.7%	OK	25.456	25.461	25.459	25.512	25.511	25.480	-0.020	20.1%	OK	25.461	25.461	25.496	25.515	25.503	25.487	-0.013	12.8%	OK	HD
48 H	②-7	A11	25.5	0.1	0.1	25.449	25.444	25.486	25.501	25.492	25.474	-0.026	25.7%	OK	25.443	25.447	25.446	25.499	25.505	25.468	-0.032	32.0%	OK	25.446	25.446	25.487	25.507	25.496	25.476	-0.024	23.6%	OK	HD
48 H	②-8	A11	25.5	0.1	0.1	25.459	25.454	25.491	25.504	25.495	25.481	-0.019	19.4%	OK	25.453</td																		



浙江柏明胜医疗科技有限公司
Zhejiang Boomingshing Medical Technology Co.,Ltd.

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文件类型 Document Type		质量记录 / Quality Record		标题 Title		尺寸检测记录 / Dimensional Inspection Record				记录编号 Record No.:		CL231220001		页码 Page																			
顾客名称/编号 Customer Name/No.		Roche/266		产品名称 Project Name		Assay-rack plain		组件名称 Part Name		AssayTip/AssayCup tray				检验依据 Test basis		ZB-SIP-12009-A1 罗氏E2C底托尺寸检验规范附件 Annex to Roche E2C Dimension standard inspection specification of Assay-Rack plain																	
图纸编号 Drawing No.		5690030001		图纸版本号 Drawing versions		0		生产线Product line		<input checked="" type="checkbox"/> E2_M_029 " E2_M_030				原料类型 Material Type		<input checked="" type="checkbox"/> 原料 Material 口水口料degraded material <input type="checkbox"/> %原料Material+__%口水料degraded material		color Green		Tolerance below 50%													
模具编号 Mold No.		<input checked="" type="checkbox"/> CH2022085D <input type="checkbox"/> CH2022054D		抽样日期/时间 Sampling Date/Time		2023.12.24		批号Lot		S23120006				阶段 stage		<input checked="" type="checkbox"/> 试模Test mould <input checked="" type="checkbox"/> 正常生产 nominal <input type="checkbox"/> 其他others		Yellow		50%~80%													
抽样水平 Level of sampling		ISO2859 S4		抽样数量 Sampling Quality		2.5模/次 2.5shots/time (Middle)		接收标准 AQL		AQL=0.15;AC/RE=0/1				单位 Unit		mm				Dark Yellow		80%~100%											
测试结果Measured dimensions/复测结果double Measured dimensions																		Red		above 100%													
检测时间 Inspection Time	Dimension (info from drawing)			Tolerances		首件 08:00-12:00				AVERAGE	Deviation*	Used tol.%*	Result	巡检 12:00-16:00				AVERAGE	Deviation*	Used tol.%*	Result	巡检 16:00-20:00											
	球标	图区	Nominal*	+	-	JH01_1	JH01_2	JH02_1	JH02-2					JH02_3	JH01_1	JH01-2	JH01_3					JH02_1	JH02_2	JH01_1	JH01_2	JH02_1	JH02_2	JH02_3	AVERAGE	Deviation*	Used tol.%*	Result	JH01_1
48 H	<input checked="" type="checkbox"/>	B3	65	0.2	0.2	64.979	64.974	64.987	65.002	64.985	64.985	-0.015	7.3%	OK	64.968	64.976	64.970	64.984	64.997	64.979	-0.021	10.5%	OK	64.976	64.969	64.976	64.978	64.979	64.976	-0.024	12.0%	OK	HD
48 H	<input checked="" type="checkbox"/>	B3	65	0.2	0.2	65.002	64.999	64.965	64.967	64.971	64.981	-0.019	9.5%	OK	64.993	65.002	64.998	64.967	64.983	64.989	-0.011	5.7%	OK	64.997	64.995	64.967	64.980	64.987	64.981	-0.019	9.4%	OK	HD
48 H	<input checked="" type="checkbox"/>	B3	65	0.2	0.2	64.952	64.946	64.970	64.990	64.980	64.967	-0.033	16.3%	OK	64.944	64.948	64.947	64.989	64.997	64.985	-0.035	17.6%	OK	64.947	64.947	64.975	64.997	64.981	64.969	-0.031	15.4%	OK	HD
48 H	<input checked="" type="checkbox"/>	B3	65	0.2	0.2	64.976	64.968	65.019	65.011	64.994	64.994	-0.008	2.9%	OK	64.968	64.970	64.972	65.021	65.036	64.993	-0.007	3.5%	OK	64.970	64.968	65.009	65.032	65.018	64.999	-0.001	0.4%	OK	HD
48 H	<input checked="" type="checkbox"/>	E17	4.17	0.08	0.08	4.138	4.153	4.150	4.130	4.127	4.140	-0.030	38.0%	OK	4.126	4.139	4.148	4.134	4.139	4.137	-0.033	41.2%	OK	4.135	4.132	4.131	4.149	4.148	4.139	-0.031	38.9%	OK	OMM
48 H	<input checked="" type="checkbox"/>	E17	4.17	0.08	0.08	4.125	4.135	4.127	4.122	4.119	4.126	-0.044	55.3%	OK	4.116	4.134	4.128	4.115	4.119	4.123	-0.048	59.4%	OK	4.135	4.141	4.128	4.128	4.132	4.133	-0.037	46.4%	OK	OMM
48 H	<input checked="" type="checkbox"/>	E17	4.17	0.08	0.08	4.102	4.149	4.133	4.116	4.111	4.122	-0.048	59.9%	OK	4.123	4.139	4.148	4.136	4.126	4.134	-0.036	44.5%	OK	4.143	4.133	4.126	4.120	4.137	4.132	-0.038	47.8%	OK	OMM
48 H	<input checked="" type="checkbox"/>	E17	4.17	0.08	0.08	4.115	4.112	4.128	4.134	4.138	4.125	-0.045	55.9%	OK	4.126	4.131	4.126	4.140	4.149	4.134	-0.036	44.9%	OK	4.134	4.136	4.148	4.148	4.140	4.140	-0.030	37.4%	OK	OMM
48 H	<input checked="" type="checkbox"/>	E17	4.17	0.08	0.08	4.105	4.137	4.155	4.139	4.141	4.136	-0.035	43.1%	OK	4.147	4.138	4.142	4.152	4.159	4.148	-0.022	27.7%	OK	4.148	4.129	4.160	4.157	4.145	4.148	-0.022	27.8%	OK	OMM
48 H	<input checked="" type="checkbox"/>	E17	4.17	0.08	0.08	4.092	4.134	4.115	4.131	4.130	4.120	-0.050	62.3%	OK	4.131	4.132	4.149	4.148	4.138	4.140	-0.030	38.1%	OK	4.130	4.136	4.154	4.143	4.128	4.138	-0.032	39.9%	OK	OMM
48 H	<input checked="" type="checkbox"/>	E17	4.17	0.08	0.08	4.128	4.130	4.125	4.129	4.132	4.129	-0.041	51.4%	OK	4.131	4.141	4.126	4.133	4.131	4.132	-0.038	47.0%	OK	4.142	4.136	4.130	4.132	4.135	4.135	-0.035	43.4%	OK	OMM
48 H	<input checked="" type="checkbox"/>	B8	66.7	0.6	0.6	66.678	66.675	66.677	66.677	66.678	66.679	-0.021	3.5%	OK	66.668	66.674	66.667	66.671	66.680	66.672	-0.028	4.7%	OK	66.673	66.668	66.663	66.670	66.669	66.669	-0.031	5.2%	OK	HD
48 H	<input checked="" type="checkbox"/>	B8	66.7	0.6	0.6	66.675	66.677	66.658	66.680	66.683	66.675	-0.025	4.2%	OK	66.672	66.694	66.684	66.712	66.691	66.672	-0.009	1.5%	OK	66.698	66.687	66.711	66.710	66.699	66.699	-0.001	0.1%	OK	HD
48 H	<input checked="" type="checkbox"/>	B8	66.7	0.6	0.6	66.690	66.689	66.656	66.660	66.672	66.672	-0.028	4.6%	OK	66.679	66.689	66.685	66.672	66.676	66.676	-0.024	4.0%	OK	66.684	66.682	66.656	66.668	66.659	66.670	-0.030	5.0%	OK	HD
48 H	<input checked="" type="checkbox"/>	B8	66.7	0.6	0.6	66.657	66.657	66.662	66.677	66.674	66.666	-0.034	5.7%	OK	66.644	66.665	66.655	66.670	66.691	66.665	-0.035	5.8%	OK	66.665	66.657	66.673	66.683	66.687	66.673	-0.027	4.5%	OK	HD
48 H	<input checked="" type="checkbox"/>	B8	66.7	0.6	0.6	66.634	66.630	66.644	66.662	66.659	66.646	-0.054	9.0%	OK	66.627	66.628	66.630	66.681	66.669	66.643	-0.057	9.5%	OK	66.629	66.630	66.648	66.670	66.654	66.646	-0.054	9.0%	OK	HD
48 H	<input checked="" type="checkbox"/>	B8	66.7	0.6	0.6	66.639	66.639	66.617	66.630	66.643	66.635	-0.065	10.8%	OK	66.630	66.668	66.654	66.659	66.676	66.659	-0.041	6.8%	OK	66.666	66.655	66.650	66.676	66.674	66.664	-0.036	5.9%	OK	HD
48 H	<input checked="" type="checkbox"/>	B8	66.7	0.6	0.6	66.648	66.640	66.654	66.667	66.667	66.657	-0.043	7.2%	OK	66.633	66.638	66.641	66.675	66.688	66.655	-0.045	7.5%	OK	66.640	66.638	66.662	66.684	66.671	66.659	-0.041	6.9%	OK	HD
48 H	<input checked="" type="checkbox"/>	B8	66.7	0.6	0.6	66.510	66.510	66.532	66.549	66.554	66.531	-0.169	28.2%	OK	66.514	66.530	66.525	66.577	66.588	66.547	-0.153	25.5%	OK	66.539	66.529	66.563	66.593	66.587	66.562	-0.138	22.9%	OK	HD
48 H	<input checked="" type="checkbox"/>	R9	0	0.2	0	0.021	0.018	0.048	0.038	0.033	0.032	0.032	15.8%	OK	0.109	0.022	0.026	0.039	0.050	0.049	0.049	24.6%	OK	0.025	0.021	0.035	0.047	0.037	0.033	0.033	16.5%	OK	OMM
48 H	<input checked="" type="checkbox"/>	R9	0	0.2	0	0.012	0.034	0.040	0.040	0.050	0.035	0.035	17.6%	OK	0.110	0.018	0.023	0.051	0.062	0.053	0.053	26.4%	OK	0.029	0.017	0.060	0.055	0.055	0.043	0.043	21.6%	OK	OMM
48 H	<input checked="" type="checkbox"/>	S9	0	0.2	0	0.055	0.067	0.033	0.039	0.046	0.046	0.046	23.0%	OK	0.118	0.076	0.065	0.059	0.074	0.074	0.074	37.2%	OK	0.062	0.067	0.059	0.052	0.061	0.060	0.060	30.1%	OK	OMM
48 H	<input checked="" type="checkbox"/>	P3	157.3	0.3	0.3	157.412	157.398	157.379	157.391	157.372	157.391	0.091	30.3%	OK	157.403	157.389	157.424	157.350	157.359	157.385	0.085	28.3%	OK	157.400	157.393	157.339	157.330	157.329	157.358	0.058	19.4%	OK	OMM
48 H	<input checked="" type="checkbox"/>	P3	157.3	0.3	0.3	157.443	157.438	157.371	157.405	157.411	0.111	37.1%	OK	157.419	157.411	157.441	157.371	157.404	157.404	0.104	34.6%	OK	157.432	157.422	157.361	157.349	157.351	157.383	0.083	27.6%	OK	OMM	
48 H	<input checked="" type="checkbox"/>	P9	157.3	0.3	0.8	157.492	157.473	157.413	157.442	157.448	0.153	51.1%	OK	157.460	157.459	157.469	157.422	157.437	157.449	0.149	49.8%	OK	157.469	157.441	157.384	157.374	157.373	157.408	0.108	36.1%	OK	OMM	
48 H	<input checked="" type="checkbox"/> </																																

PQ3 Report for E2G_Assay-rack plain

f3 BOOMINGSHING
MEDICAL

浙江柏明胜医疗科技有限公司
Zhejiang Boomingshing Medical Technology Co.,Ltd.

文件编号
Doc. No.
版本号

ZB-QR-12075

文件类型 Document Type		质量记录 / Quality Record		标题 Title		尺寸检测记录 / Dimensional Inspection Record			记录编号 Record No.:	CL231220001		页码 Page																				
顾客名称/编号 Customer Name/No.		Roche/266		产品名称 Project Name		Assay-rack plain		组件名称 Part Name	AssayTip/AssayCup tray		检验依据 Annex to Roche E2G Dimension standard inspection specification of Assay-Rack plain			color	Tolerance																	
图纸编号 Drawing No.		5690030001		图纸版本号 Drawing versions		0		生产线Product line	<input checked="" type="checkbox"/> E2_M_029 ~ E2_M_030		原料类型 Material Type	<input type="checkbox"/> 原料 Material 口水口料degraded material <input type="checkbox"/> _____% 原料Material+_____%水口料degraded material			Green	below 50%																
模具编号 Mold No.		<input checked="" type="checkbox"/> CH2022085D <input type="checkbox"/> CH20220254D		抽样日期/时间 Sampling Date/Time		2023.12.24		批号Lot	S23120006		阶段 stage	<input type="checkbox"/> 试模Test mould <input checked="" type="checkbox"/> 正常生产 nominal <input type="checkbox"/> 其他others	口验证qualification		Yellow	50%~80%																
抽样水平 Level of sampling		ISO2859 S4		抽样数量 Sampling Quality		2.5模/次 2.5shots/time (Middle)		接收标准 AQL	AQL=0.15; AC/RE=0/1		单位 Unit	mm		Dark Yellow	80%~100%																	
														Red	above 100%																	
测试结果Measured dimensions/复测结果double Measured dimensions																																
检测时间 Inspection Time	Dimension (info from drawing)		Tolerances		末件 20:00-0:00				AVERAGE	Deviation*	Used tol.%*	Result	AVERAGE	Deviation*	Used tol.%*	Result	AVERAGE	Deviation*	Used tol.%*	Result	AVERAGE	Deviation*	Used tol.%*	Result	测量设备 measuring equipment							
	球标	图区	Nominal*	+	-	JH01_1	JH01_2	JH01_3																		JH02_1	JH02_2					
48 H	<input checked="" type="checkbox"/>	B3	65	0.2	0.2	64.982	64.981	64.987	64.995	64.994	64.988	-0.012	6.1%	OK -											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	HD
48 H	<input checked="" type="checkbox"/>	B3	65	0.2	0.2	65.006	65.017	65.011	64.985	64.995	65.003	0.003	1.3%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	HD
48 H	<input checked="" type="checkbox"/>	B3	65	0.2	0.2	64.957	64.984	64.968	65.009	65.035	64.986	-0.014	6.9%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	HD
48 H	<input checked="" type="checkbox"/>	B3	65	0.2	0.2	64.973	64.981	64.985	65.035	65.050	65.005	0.005	2.3%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	HD
48 H	<input checked="" type="checkbox"/>	E17	4.17	0.08	0.08	4.137	4.138	4.148	4.147	4.149	4.144	-0.026	33.0%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	OMM
48 H	<input checked="" type="checkbox"/>	E17	4.17	0.08	0.08	4.146	4.137	4.142	4.122	4.137	4.137	-0.033	41.1%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	OMM
48 H	<input checked="" type="checkbox"/>	E17	4.17	0.08	0.08	4.135	4.139	4.152	4.130	4.142	4.140	-0.031	38.1%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	OMM
48 H	<input checked="" type="checkbox"/>	E17	4.17	0.08	0.08	4.138	4.138	4.145	4.135	4.149	4.141	-0.029	36.3%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	OMM
48 H	<input checked="" type="checkbox"/>	E17	4.17	0.08	0.08	4.141	4.139	4.149	4.156	4.162	4.150	-0.020	25.4%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	OMM
48 H	<input checked="" type="checkbox"/>	E17	4.17	0.08	0.08	4.131	4.148	4.139	4.151	4.146	4.143	-0.027	34.0%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	OMM
48 H	<input checked="" type="checkbox"/>	E17	4.17	0.08	0.08	4.148	4.140	4.149	4.144	4.152	4.147	-0.023	29.1%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	OMM
48 H	<input checked="" type="checkbox"/>	B8	66.7	0.6	0.6	66.685	66.681	66.690	66.684	66.679	66.685	-0.015	2.6%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	HD
48 H	<input checked="" type="checkbox"/>	B8	66.7	0.6	0.6	66.692	66.716	66.725	66.718	66.728	66.716	0.016	2.6%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	HD
48 H	<input checked="" type="checkbox"/>	B8	66.7	0.6	0.6	66.695	66.706	66.702	66.679	66.680	66.693	-0.007	1.2%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	HD
48 H	<input checked="" type="checkbox"/>	B8	66.7	0.6	0.6	66.666	66.681	66.693	66.698	66.701	66.688	-0.012	2.0%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	HD
48 H	<input checked="" type="checkbox"/>	B8	66.7	0.6	0.6	66.642	66.647	66.653	66.684	66.703	66.666	-0.034	5.7%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	HD
48 H	<input checked="" type="checkbox"/>	B8	66.7	0.6	0.6	66.659	66.684	66.689	66.682	66.708	66.684	-0.016	2.6%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	HD
48 H	<input checked="" type="checkbox"/>	B8	66.7	0.6	0.6	66.646	66.654	66.659	66.694	66.707	66.672	-0.028	4.7%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	HD
48 H	<input checked="" type="checkbox"/>	B8	66.7	0.6	0.6	66.535	66.552	66.555	66.599	66.627	66.574	-0.126	21.0%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	HD
48 H	<input checked="" type="checkbox"/>	R9	0	0.2	0	0.011	0.002	0.021	0.040	0.043	0.023	0.023	11.7%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	OMM
48 H	<input checked="" type="checkbox"/>	R9	0	0.2	0	0.030	0.018	0.017	0.067	0.063	0.039	0.039	19.5%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	OMM
48 H	<input checked="" type="checkbox"/>	S9	0	0.2	0	0.065	0.074	0.053	0.054	0.051	0.060	0.060	29.8%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	OMM
48 H	<input checked="" type="checkbox"/>	P3	157.3	0.3	0.3	157.422	157.435	157.448	157.449	157.426	157.436	0.136	45.3%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	OMM
48 H	<input checked="" type="checkbox"/>	P3	157.3	0.3	0.3	157.438	157.466	157.494	157.458	157.439	157.459	0.159	53.0%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	OMM
48 H	<input checked="" type="checkbox"/>	P9	157.3	0.3	0.8	157.465	157.478	157.531	157.508	157.480	157.492	0.192	64.0%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	OMM
48 H	<input checked="" type="checkbox"/>	S7	156.65	0.3	0.3	156.732	156.750	156.767	156.708	156.683	156.728	0.078	26.0%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	OMM
48 H	<input checked="" type="checkbox"/>	S7	156.65	0.3	0.3	156.673	156.667	156.672	156.665	156.652	156.666	0.016	5.3%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	OMM
48 H	<input checked="" type="checkbox"/>	S5	156.65	0.3	1	156.821	156.665	156.714	156.630	156.610	156.688	0.038	12.6%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	OMM
48 H	<input checked="" type="checkbox"/>	N3	128.44	0.3	0.3	128.565	128.580	128.584	128.551	128.541	128.564	0.124	41.4%	OK											#DIV/0!	#DIV/0!	#DIV/0!		#DIV/0!	#DIV/0!	#DIV/0!	OMM

结论conclusion: OK NG

测量员/日期Inspector/Date: *邹71n 2023.12.27*

复核人/日期reviewer/Date: *2023.12.27*

P03

浙江柏明胜医疗器械有限公司
Shenzhen Boomingshing Medical Devices Co., Ltd

首件检查/尺寸测量表

浙江柏明胜医疗器械有限公司
Shenzhen Boommingshing Medical Devices Co., Ltd

首件检查/尺寸测量表

浙江柏明胜医疗器械有限公司
Shenzhen Boomingshing Medical Devices Co., Ltd

首件检查/尺寸测量表

浙江柏明胜医疗器械有限公司
Shenzhen Boomingshing Medical Devices Co., Ltd

首件检查/尺寸测量表

First Article Inspection / Dimension Measure Form: VICIVISION

客户/Customer:	266	生产订单 Job No.: ZBS0602-231200013														检验日期/Date:	2024.01.04	编号Number:																			
机台号 Machine No.:	ZB-K-31-0021	模具编号 Mould Nos.	CH202208GD			生产订单 Job No.:				品名: Name:	E2G cup			<input type="checkbox"/>	首件检查 First article inspection 结构尺寸检查 Structural size check																						
材料: Material:	PP BORMED W RJ880M0	模具穴数 Mold cavity:	1*64			批次号 (Lot No.):	23003908			产出穴数 Number of output points:	1*64			<input type="checkbox"/>	产品阶段/Product phase:	<input type="radio"/> Q0	<input type="radio"/> PQ1	<input type="radio"/> PQ2	<input checked="" type="radio"/> PQ3	<input type="radio"/> MP																	
														<input type="checkbox"/>	Q0阶段/QQ phase:	<input type="radio"/> Nom	<input type="radio"/> Min	<input type="radio"/> Max	<input type="radio"/> n/a																		
序号 Item No.	图纸尺寸 编号	抽样日期/时间 Sampling Date/Time	2023.12.30 (48H after cooling size)										Time:		文件: 20:00-00:00		留样日期/Sample Date				2023.12.30				检测工具 Used tool	判断结果 Judgment(OK or NG)											
			33#	34#	35#	36#	37#	38#	39#	40#	41#	42#	43#	44#	45#	46#	47#	48#	49#	50#	51#	52#	53#	54#			55#	56#	57#	58#	59#	60#	61#	62#	63#	64#	
1	PM02	7±0.05 (6.95-7.05) mm	7.002	7.005	7.003	6.998	7.000	6.998	6.998	7.015	7.002	6.991	7.019	7.006	7.009	6.999	6.994	6.996	7.004	6.997	6.999	7.011	7.002	6.999	6.998	6.998	6.994	7.013	6.993	7.000	7.002	6.997	6.998	7.000	ViciVision	OK	
2	PM02	7±0.05 (6.95-7.05) mm	6.982	6.985	6.983	6.982	6.981	6.981	6.982	6.974	6.982	6.974	6.985	6.99	6.986	6.986	6.982	6.980	6.975	6.982	6.979	6.986	6.976	6.990	6.973	6.972	6.981	7.005	6.971	6.982	6.983	6.979	6.983	ViciVision	OK		
3	PM05	26±0.25/-0.1 (25.9-26.25) mm	26.177	26.171	26.141	26.152	26.157	26.151	26.146	26.133	26.180	26.124	26.183	26.116	26.129	26.151	26.155	26.121	26.101	26.125	26.111	26.142	26.153	26.133	26.140	26.121	26.120	26.163	26.126	26.166	26.181	26.134	26.152	26.144	ViciVision	OK	
4	PM07	≤1.5mm	0.103	0.074	0.057	0.126	0.094	0.185	0.146	0.072	0.097	0.140	0.135	0.112	0.110	0.066	0.097	0.109	0.123	0.102	0.053	0.143	0.105	0.072	0.209	0.066	0.106	0.062	0.099	0.099	0.153	0.113	0.110	0.080	0.119	OMM	OK
5	PM07	≤0.4mm	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000	OMM	OK		
		剖开检查/ Perform inspect after splitting	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	Visual/目视	OK	
		外观检查 Visual inspection	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	Visual/目视	OK	
		结构、材料、规格检查 Structural material and size inspection	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	Visual/目视	OK	
结论 conclusion:		<input checked="" type="checkbox"/> OK <input type="checkbox"/> NG																																			
检验员/日期 IPQC/Date		Jin Xu 2024.01.04										审核/日期 Checked by Date		Zuy Lv 2024.01.04														Form No.: ZB-QR-12075									

P02

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浙江柏明胜医疗器械有限公司
Shenzhen Boomingshing Medical Devices Co., Ltd

首件检查/尺寸测量表

首件检查/尺寸测量表
First Article Inspection / Dimension Measure Form: VICIVISION

浙江柏明胜医疗器械有限公司
Shenzhen Boomingshing Medical Devices Co., Ltd

首件检查/尺寸测量表

First Article Inspection / Dimension Measure Form: VICIVISION

客户/Customer:		R266	生产订单 Job No.: ZBS0602-231200010 品名: Name: E2G TIP																			检验日期/Date:		2024.01.04		编号/Number:										
机台号 Machine No:		ZB-K-31-0020	模具编号 Mould No:		CH2022087D				生产订单 Job No:		ZBS0602-231200010						品名: Name:		E2G TIP			<input checked="" type="radio"/> 首件检查 First article inspection														
材料: Material:		PP PRE-ELEC TP16650	模具穴数 Mold cavity:		1*64				批次号 (Lot No.):		23003908						产出穴数 Number of output points:		1*64			<input type="radio"/> 结构尺寸检查 Structural size check														
序号 Item No.	图示尺寸 Drawing dimension	抽样日期/时间 Sampling Date/Time		2023.12.30 (48H after cooling size)														<input type="radio"/> 白班 Day shift 时间段		<input checked="" type="radio"/> 夜班 Night shift 时间段		Time:		未件 20:00-00:00		留样日期/Sample Date		2023.12.30						检避工具 Used tool	判断结果 Judgment OK or NG	
		测样项目 Item		1#	2#	3#	4#	5#	6#	7#	8#	9#	10#	11#	12#	13#	14#	15#	16#	17#	18#	19#	20#	21#	22#	23#	24#	25#	26#	27#	28#	29#	30#			31#
1	PM01	6±0.05 (5.95-6.05) mm	6.013	6.020	5.993	6.028	6.018	5.998	6.021	6.016	6.016	6.001	6.018	6.001	6.013	6.007	5.994	6.015	6.006	6.000	6.015	5.992	6.004	5.996	6.021	6.001	6.028	6.005	6.004	5.993	5.991	6.023	5.991	6.017	Vicivision	OK
2	PM05	48±0.2 (47.8-48.25) mm	48.001	48.010	48.028	48.000	48.015	48.015	48.003	48.022	48.009	48.036	47.992	48.030	48.011	48.031	48.062	48.023	48.025	48.071	48.027	48.047	48.010	48.035	48.018	48.067	48.004	48.020	48.040	48.045	48.047	48.054	48.033	48.013	Vicivision	OK
3	PM18	Max0.7(0-0.73) mm	0.338	0.206	0.214	0.537	0.572	0.283	0.152	0.186	0.390	0.063	0.390	0.354	0.500	0.246	0.055	0.433	0.495	0.587	0.524	0.347	0.142	0.607	0.685	0.570	0.613	0.379	0.308	0.381	0.397	0.484	0.578	0.581	Vicivision	OK
4	PM20	0.35±0.025 (0.325-0.375) mm	0.349	0.352	0.351	0.352	0.350	0.349	0.355	0.348	0.351	0.348	0.351	0.351	0.351	0.348	0.347	0.349	0.348	0.348	0.354	0.354	0.349	0.353	0.350	0.350	0.350	0.351	0.351	0.350	0.349	0.349	0.355	OMM	OK	
5	PM03	3.96±0.03 (3.93-3.990) mm	3.948	3.939	3.940	3.944	3.950	3.941	3.946	3.940	3.940	3.953	3.951	3.947	3.948	3.950	3.950	3.942	3.949	3.947	3.952	3.950	3.947	3.948	3.942	3.944	3.955	3.944	3.945	3.947	3.950	3.948	3.951	3.948	CMM	OK
6	PM27	Max 0.1(0-0.1) mm	0.037	0.046	0.050	0.032	0.033	0.043	0.027	0.036	0.049	0.028	0.039	0.040	0.038	0.021	0.03	0.022	0.038	0.037	0.040	0.039	0.032	0.038	0.032	0.047	0.027	0.039	0.031	0.031	0.035	0.024	0.024	0.027	CMM	OK
7	PM15	≤0.1mm	0.018	0.022	0.015	0.018	0.026	0.012	0.007	0.015	0.009	0.006	0.012	0.007	0.019	0.013	0.024	0.027	0.013	0.022	0.016	0.034	0.013	0.027	0.020	0.021	0.015	0.023	0.016	0.011	0.030	0.023	0.048	0.025	OMM	OK
8	PM01	≤0.1mm	0.059	0.047	0.031	0.049	0.036	0.028	0.039	0.045	0.034	0.035	0.028	0.041	0.012	0.033	0.041	0.030	0.048	0.039	0.026	0.016	0.027	0.045	0.028	0.037	0.032	0.037	0.018	0.025	0.046	0.018	0.047	OMM	OK	
9	PM05	≤0.15mm	0.067	0.105	0.052	0.054	0.070	0.078	0.051	0.075	0.110	0.071	0.082	0.068	0.084	0.088	0.077	0.029	0.067	0.063	0.087	0.131	0.096	0.018	0.116	0.059	0.023	0.040	0.070	0.039	0.047	0.051	0.088	0.078	OMM	OK
10	PM05	≤0.2mm	0.090	0.057	0.087	0.083	0.113	0.058	0.078	0.081	0.076	0.076	0.025	0.152	0.030	0.115	0.023	0.023	0.058	0.034	0.057	0.083	0.063	0.073	0.026	0.031	0.078	0.018	0.026	0.053	0.085	0.102	0.063	0.168	HD	OK
剖开检查/ Perform inspection after splitting				OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	Visual/目视	OK
外观检查 Visual inspection				OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	Visual/目视	OK	
结构、材料、规格检查 Structural, material and size inspection				OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	Visual/目视	OK		
结论Conclusion: <input checked="" type="checkbox"/> OK <input type="checkbox"/> NG																																				
检验员/日期 IPQC/Date		Yan Wang 2024.01.04														审核人/日期 Checked by/Date		Zwy Lv 2024.01.04														Form No.: ZB-QR-12075				

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浙江柏明胜医疗器械有限公司
Shenzhen Boomingshing Medical Devices Co., Ltd

首件检查/尺寸测量表

First Article Inspection / Dimension Measure Form: VICIVISION

客户/Customer:		R266	生产订单 Job No.: ZBS0602-231200010																		检验日期/Date:		2024.01.04				编号/Number:																																		
机台号 Machine No.:		ZB-K-31-0020	模具编号 Mould No.:	CH2022087D				生产订单 Job No.:		ZBS0602-231200010				品名: Name:		E2G TIP				<input checked="" type="radio"/> 首件检查 First article inspection <input type="radio"/> 结构尺寸检查 Structural size check		产品阶段/Product phase: <input type="radio"/> OQ <input type="radio"/> PQ1 <input type="radio"/> PQ2 <input type="radio"/> PQ3 <input type="radio"/> MP OQ阶段/OQ phase: <input type="radio"/> Nom <input type="radio"/> Min <input type="radio"/> Max <input type="radio"/> n/a																																							
材料: Material:		PP PRE-ELEC TP16650	模具穴数 Mold cavity:	1*64				批次号 (Lot No.):		23003908				产出穴数 Number of output points:		1*64																																													
序号 Item No.	图纸尺寸 编号 Dimension Drawing No.	抽样日期/时间 Sampling Date/Time:		2023.12.30 (48H after cooling size)																		<input type="radio"/> 白班 Day shift: 时间段 <input type="radio"/> 夜班 Night shift: 时间段		Time:		末件 20:00-00:00				留样日期/Sample Date 2023.12.30				检测工具 Used tool	判断结果 Judgment(OK or NG)																										
		33#	34#	35#	36#	37#	38#	39#	40#	41#	42#	43#	44#	45#	46#	47#	48#	49#	50#	51#	52#	53#	54#	55#	56#	57#	58#	59#	60#	61#	62#	63#	64#																												
1	PM01	6±0.05 (5.95-6.05) mm	6.004	5.995	6.015	5.995	5.992	6.009	5.998	5.998	5.992	6.008	5.998	5.995	5.993	6.010	6.019	6.007	6.015	5.996	6.002	6.005	5.999	5.995	6.009	6.008	6.003	6.006	5.996	6.006	5.999	6.005	6.015	5.996	Vicivision	OK																									
2	PM05	48±0.2 (47.8-48.25) mm	48.022	48.039	48.007	48.048	48.043	48.037	48.018	48.035	48.043	48.021	48.032	48.059	48.025	48.034	48.002	48.043	48.024	48.047	48.013	48.026	48.039	48.047	48.023	48.021	48.017	48.017	48.032	48.027	48.033	48.040	48.018	48.014	48.055	Vicivision	OK																								
3	PM18	Max0.7 (0-0.73) mm	0.511	0.536	0.349	0.530	0.648	0.540	0.515	0.279	0.554	0.509	0.613	0.690	0.489	0.474	0.439	0.401	0.530	0.655	0.467	0.519	0.090	0.103	0.285	0.498	0.376	0.223	0.118	0.410	0.318	0.295	0.535	0.194	Vicivision	OK																									
4	PM20	0.35±0.025 (0.325-0.375) mm	0.349	0.347	0.354	0.350	0.343	0.346	0.353	0.347	0.349	0.353	0.359	0.347	0.352	0.352	0.352	0.348	0.351	0.353	0.354	0.350	0.351	0.351	0.354	0.353	0.359	0.349	0.349	0.348	0.348	0.351	0.346	0.352	OMM	OK																									
5	PM03	3.96±0.03 (3.93-3.99) mm	3.944	3.946	3.946	3.944	3.947	3.944	3.952	3.949	3.951	3.947	3.945	3.948	3.949	3.946	3.946	3.945	3.951	3.952	3.955	3.949	3.945	3.949	3.951	3.951	3.953	3.944	3.947	3.950	3.949	3.950	3.946	3.950	CMM	OK																									
6	PM27	Max 0.1 (0-0.1) mm	0.034	0.022	0.045	0.047	0.041	0.048	0.033	0.032	0.026	0.033	0.026	0.029	0.044	0.051	0.034	0.028	0.020	0.025	0.022	0.031	0.031	0.018	0.031	0.030	0.046	0.039	0.038	0.022	0.044	0.046	0.022	0.015	CMM	OK																									
7	PM11	≤0.1mm	0.058	0.012	0.018	0.047	0.039	0.030	0.014	0.027	0.027	0.024	0.030	0.077	0.052	0.028	0.016	0.033	0.018	0.023	0.020	0.021	0.011	0.010	0.008	0.021	0.018	0.010	0.013	0.024	0.013	0.012	0.033	0.026	OMM	OK																									
8	PM1	≤0.1mm	0.022	0.025	0.038	0.027	0.019	0.046	0.019	0.024	0.026	0.034	0.035	0.028	0.019	0.034	0.039	0.030	0.037	0.023	0.026	0.033	0.023	0.025	0.033	0.028	0.029	0.000	0.022	0.035	0.029	0.025	0.029	0.024	OMM	OK																									
9	PM5	≤0.15mm	0.098	0.098	0.036	0.073	0.066	0.088	0.057	0.072	0.099	0.057	0.058	0.085	0.097	0.077	0.043	0.043	0.075	0.067	0.097	0.123	0.063	0.022	0.110	0.065	0.043	0.040	0.028	0.052	0.076	0.072	0.096	0.097	OMM	OK																									
10	PM5	≤0.2mm	0.063	0.048	0.051	0.052	0.080	0.016	0.040	0.050	0.084	0.100	0.075	0.135	0.070	0.075	0.012	0.072	0.062	0.131	0.107	0.096	0.112	0.101	0.090	0.083	0.070	0.033	0.111	0.189	0.150	0.074	0.052	0.100	HD	OK																									
		剖开检查/ Perform inspection after splitting																		OK		外观检查/ Visual inspection																		OK		结构、材料、规格检查/ Structural, material and size inspection																		OK	
检验员/日期 IPQC/Date:		Yan Wang 2024.01.04																		审核/日期 Checked by/Date:		Ziyi Lv 2024.01.04																		Form No.: ZB-QR-12075																					

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Certificate of Compliance

Customer (客户) : Roche Diagnostics GmbH Sandhofer Strasse 116 68305 Mannheim/Germany

Product Name (产品名称) : AssayTip/AssayCup tray

Lot Number (批次) : 23003908

Global Material No. (总部物料编号) : 05694302001

QC- Material No. (QC 样板物料编号) : 0048020970

Technical Terms of Delivery (TDC 编号) : 10339799

Quantity (数量) : 134CTN

T_{DOM} (生产日期) : 2023.12.24

T₀ (生产日期) : 2023.12.24

T_v (失效日期) : 2025.11.30

Comment (备注) : PQ3

We hereby certify that the above mentioned product and batch has been manufactured in full compliance with the current Good Manufacturing Practice requirements and technical terms of delivery and has been tested according to the current specifications.

我们在此保证以上提到的产品和批次严格按照现行有效的良好管理规范的要求生产，产品技术要求符合客户 TDC 的要求，并按照现行有效的规格实施检测，符合要求。

Mark Liang *Henry Wang*
创建人/日期 Prepared by/Date: 2024.01.06 批准人/日期 Approved by/Date: 2024.01.06