



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

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2023年YY10月
MM23日DD

文件类型
DOC.Type

质量记录
Quality Record

文件编号
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ZB-QR-12051

页码
Page

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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 BMS0606-231200042
Job No:

批次号 2303908
Lot No:

品名 Assay-rack-Satck
Name:

模具穴数 N/A
Mold cavity:

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:

0Q□ PQ1□ PQ2□ MP量产口

OQ阶段
OQ phase:

中值Nom□ 高值Max□ 低值Min□

检查项目 Inspection item	时间/Time	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 acording to relevant Standard Inspection Procedure ,Gold sample&limit board, etc	核对首件FAI check	OK	OK	OK	OK	OK	OK	OK	OK				
	材料/颜色 Material/color	OK	OK	OK	OK	OK	OK	OK	OK				
	外观检查 Appearance check	OK	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	N/A				R
	包装袋/标签检查 Packing label check	OK	OK	OK	OK	OK	OK	OK	OK				
	包装检查 Packing check	OK	OK	OK	OK	OK	OK	OK	OK				
	尺寸 Dimension	See attached dimension report											

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				N							

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				R
	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												

白天QC/日期 Day shift QC/Date:	王晓军	审核/日期 Checked by/Date:	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	审核/日期 Checked by/Date:	许玉	夜班QC/日期 Night shift QC/Date:	2023.12.30
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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	文件编号 Doc. No.	页码 Page	1/1				
品名 Part name	<i>Assy Tip/Assy cup tray</i>			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.	<i>134</i>			□ 正常 Normal □ 加严 Tighten Inspection □ 全检 100% Inspection □ 其它 Other						
抽样标准Sampling Standard ISO2859-1	抽样数 Sample Size	20	Ac	0	Re				1	
序号 Item	检验项目 Inspection Items	检验结果 Inspection Result			判定 OK/NG					
1	包装外观(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.					
		(<i>b</i>) PCS/包 pcs/bag	(<i>b</i>) 包/内箱 bag/inner box	<i>36</i>	内箱/外箱 inner box/carton	36	PCS/箱 pcs/carton	<input checked="" type="checkbox"/> OK		
2	产品包装 Product Package	<input checked="" type="checkbox"/> 符合 Good <input type="checkbox"/> 不符合 NG			<input checked="" type="checkbox"/> OK					
	错装/混装WrongMix	<input checked="" type="checkbox"/> 无 No	<input type="checkbox"/> 有 Yes				<input checked="" type="checkbox"/> OK			
	杂物/粉尘DirtyDust	<input checked="" type="checkbox"/> 无 No	<input type="checkbox"/> 有 Yes				<input checked="" type="checkbox"/> OK			
	其他Others	<input checked="" type="checkbox"/> 无 No	<input type="checkbox"/> 有 Yes				<input checked="" type="checkbox"/> OK			
3	内、外箱票 、证书 Label, Certificate	<input checked="" type="checkbox"/> 有 Yes <input type="checkbox"/> 无 No			<input checked="" type="checkbox"/> OK					
	内容清晰/完整/正确 content clear / full / correct	<input checked="" type="checkbox"/> 有 Yes	<input type="checkbox"/> 无 No				<input checked="" type="checkbox"/> OK			
	材质、外观、颜色、规格 Material, Appearance, Color , Spec.	<input checked="" type="checkbox"/> 符合 good	<input type="checkbox"/> 不符合 No				<input checked="" type="checkbox"/> OK			
4	产品外观 Product Cosmetic	<input checked="" type="checkbox"/> 无 No <input type="checkbox"/> 有 Yes			<input checked="" type="checkbox"/> 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				<input checked="" type="checkbox"/> OK			
	异物/foreign matter	<input checked="" type="checkbox"/> 无 No	<input type="checkbox"/> 有 Yes				<input checked="" type="checkbox"/> OK			
5	产品尺寸 Dimension	规格 Spec	1	2	3	4	5	<input checked="" type="checkbox"/> OK		
								<input checked="" type="checkbox"/> OK		
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				<input checked="" type="checkbox"/> OK				
	2, 推拉力测试 Push and Pull Test				<input checked="" type="checkbox"/> OK					
	3, 透光率检测 Optical Test				<input checked="" type="checkbox"/> OK					
	4, 密封泄露测试 Leak Test				<input checked="" type="checkbox"/> OK					
	5, 其它性能测试 Other Test				<input checked="" type="checkbox"/> OK					
结果判定Conclusion		<input checked="" type="checkbox"/> 合格 Pass			<input type="checkbox"/> 不合格 NG					
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					

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. 保密密级, 敏感Confidentiality Level:

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	25.887	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	25.898	25.890	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	25.483	-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	-0.019	21.5%	OK	25.469	25.473	25.475	25.473	25.503	25.509	-0.004	3.8%	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	25.516	25.522	25.509	-0.004	4.7%	OK	HD
48 H	②-6	A11	25.5	0.1	0.1	25.472	25.467	25.498	25.521	25.508	25.493	-0.007	6.5%	OK	25.471	25.473	25.472	25.527	25.539	25.496	-0.004	3.6%	OK	25.472	25.472	25.515	25.515	25.535	25.524	-0.003	3.4%	OK	HD
48 H	②-7	A11	25.5	0.1	0.1	25.479	25.474	25.502	25.523	25.513	25.499	-0.001	1.3%	OK	25.478	25.480	25.479	25.531	25.544	25.503	-0.003	2.6%	OK	25.478	25.478	25.519	25.539	25.528	25.508	-0.008	8.4%	OK	HD
48 H	②-8	A11	25.5	0.1	0.1	25.491	25.489	25.456	25.466	25.463	25.473	-0.027	27.0%	OK	25.491	25.4																	



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

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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.:		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		ZB-SIP-12009-A1 罗氏E2G底托尺寸检验规范附件 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		E2_M_029 " E2_M_030		原料类型 Material Type		<input checked="" type="checkbox"/> 原料 Material	□水口料degraded material	<input checked="" type="checkbox"/> %原料Material+ <input type="checkbox"/> 水口料degraded material	Green		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"/> 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 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				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
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	64.998	65.019	64.994	64.994	-0.008	2.9%	OK	64.968	64.970	64.972	65.021	64.993	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	4.142	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	66.636	66.643	66.635	-0.065	10.8%	OK	66.636	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	66.675	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	66.587	66.562	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	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																													

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.
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Version

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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 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	测量设备 measuring equipment
	球标	图区	Nominal*	+	-	JH01_1	JH01_2	JH01_3	JH02_1													
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	157.509	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: *6n7/n 2023.12.27*

复核人/日期reviewer/Date: *Zuy Lv 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

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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	6.982	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	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	0.153	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	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
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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	首件检查 First article inspection <input type="radio"/> 尺寸检查 Structural size check																														
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				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																											
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)												白班Day shift: 时间段		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 (47.8-48.2) 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 (0-0.7) 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	0.116	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	0.353	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	PM17	≤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	PM11	≤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	PM05	≤0.15mm	0.098	0.098	0.036	0.073	0.066	0.088	0.057	0.072	0.098	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	PM05	≤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	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	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	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	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	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	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	
结论 conclusion: <input checked="" type="checkbox"/> OK <input type="checkbox"/> NG																																																	
检验员/日期 Inspector/Date:		Yan Wang 2024.01.04												审核/日期 Checked by/Date:		Ziyi Lv 2024.01.04												Form No.: ZB-QC-12075																					

P023

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