Product Risk Management

产品风险管理

公司名称： **Company Name:**	石家庄鸿锐集团有限公司 Shijiazhuang Hongray Group
公司地址： **Company Address:**	河北省晋州市通达路东段路南 South Tongda Rd., East Dist. Jinzhou City, Hebei , 052260,China
产　　品： **Product:**	一次性使用无粉丁腈检查用手套 Disposable Nitrile Examination Gloves, Powder Free
型　　号： **Model:**	XS, S, M, L, XL, XXL
附　　件： **Accessories:**	N/A
标　　准： **Standard:**	EN ISO 14971:2019/ISO 14971:2019
结　　论： **Result:**	所有可识别的风险都已经被评估。在采取适当的措施以降低这些风险之后，关于产品预期的应用和用途上，各种等级的风险是可以接受的。 All risks associated with the identified hazards have been evaluated. After appropriate measures to reduce these risks have been taken, the overall level of risk of the product is acceptable with regard to the intended application and use of the application.

编写 Compiled by:	Quality Dept/Risk Management Team	日期 Date:	2021.01.10
评审 Reviewed by: (Name/Title/Dept.)	Wumin/ QA Dept./Hongray Group	日期 Date:	2021.01.10
批准 Approved by: (Name/Title/Dept.)	Zhang Yaping/Management Representative/ Hongray Group	日期 Date:	2021.01.10

Product Risk Management

Company: Shijiazhuang Hongray Group Co., Ltd.
Product: Disposable Nitrile Examination Gloves, Powder Free

Identification of hazards and characteristics related to safety
表 1 可能影响安全性的特征的问题清单

#	问题清单	特征判定
1	预期用途和怎样使用：What is the intended use and how is the medical device to be used?	一次性使用，穿戴在手上 Disposable, By donning on the hand
2	是否预期植入： Is the medical device intended to be implanted?	No
3	是否接触病人或其他人：Is the medical device intended to be in contact with the patient or other persons?	接触病人和检查者 Contact patient and examiner
4	所用的元件/材料：What materials or components are utilized in the medical device or are used with, or are in contact with, the medical device?	Nitrile Latex, KOH, Sulphur, Accelerator (ZDEC/ZDBC etc), Zinc Oxide, Titanium Dioxide, Wingstay-L, Color Pigment.
5	能量给予/源于病人： Is energy delivered to or extracted from the patient?	No
6	物质给予/源于病人： Are substances delivered to or extracted from the patient?	No
7	被加工的生物材料： Are biological materials processed by the medical device for subsequent reuse, transfusion or transplantation?	No
8	灭菌/用户灭菌或其它微生物控制：Is the medical device supplied sterile or intended to be sterilized by the user, or are other microbiological controls applicable?	N/A (non-sterile products) 非灭菌产品
9	用户是否需日常清洁或消毒： Is the medical device intended to be routinely cleaned and disinfected by the user?	No
10	改变病人环境：Does the medical device modify the patient environment?	No
11	测量功能： Are measurements taken?	No
12	器械输出的数据解释： Is the medical device interpretative?	No
13	是否与其它药物或医疗技术联用：Is the medical device intended for use in conjunction with other medical devices, medicines or other medical technologies?	No
14	不需要的能量或物质输出：Are there unwanted outputs of energy or substances?	No
15	医疗器械容易受到环境影响?Is the medical device susceptible to environmental influences?	Yes, high temperature will degenerate the gloves
16	器械是否影响环境 Does the medical device influence the environment?	No

17	基本消耗品/附件 Does the medical device require consumables or accessories?	No
18	是否需要维护或校正 Is maintenance or calibration necessary?	No
19	是否包括软件 Does the medical device contain software?	No
20	Does the medical device allow access to information?	No
21	Does the medical device store data critical to patient care?	No
22	是否有严格的寿命周期 Does the medical device have a restricted shelf life?:	是，器械的寿命是 3 年 Yes, the shelf life of the device is 3 years.
23	延长/长期使用的影响 Are there any delayed or long-term use effects?	No
24	使用者或病人对器械机械力控制 To what mechanical forces will the medical device be subjected?	N/A
25	决定器械的寿命（包括老化）What determines the lifetime of the medical device?	针孔、拉力强度 Pinhole, Tensile Strength
26	一次性使用 Is the medical device intended for single use?	一次性使用 Single use
27	是否需安全退出运行或处置 Is safe decommissioning or disposal of the medical device necessary?	N/A
28	安装和使用是否需特殊培训 Does installation or use of the medical device require special training or special skills?	N/A
29	提供关于安全使用的信息 How will information for safety be provided?	在包装上标识使用说明 Indication for use will be labeled on the labelling.
30	新生产过程是否需建立或引入 Are new manufacturing processes established or introduced?	N/A
31	是否器械的成功使用，决定性的取决于人为因素，如用户接口 Is successful application of the medical device dependent on the usability of the user interface?	N/A
31.1	使用者接口设计特性是否会造成使用错误 Can the user interface design features contribute to use error?	N/A
31.2	在忙乱分心的环境中使用，医疗器械是否会导致使用错误 Is the medical device used in an environment where distractions can cause use error?	N/A
31.3	器械是否有连接部分或附件 Does the medical device have connecting parts or accessories?	N/A
31.4	是否有控制接口 Does the medical device have a control	N/A

	interface?	
31.5	器械是否显示信息 Does the medical device display information?	N/A
31.6	器械是否由菜单控制 Is the medical device controlled by a menu?	N/A
31.7	Is the successful use of the medical device dependent on a user's knowledge, skills and abilities?	N/A
31.8	器械是否由有特殊需要的人员使用 Will the medical device be used by persons with specific needs?	N/A
31.9	使用者接口是否用来发起使用者行为 Can the user interface be used to initiate unauthorised actions?	N/A
32	器械使用是否警报系统 Does the medical device include an alarm system?	N/A
33	什么方法会导致器械被故意的误用 In what ways might the medical device be misused (deliberately or not)?	没有按使用说明使用器械 Did not follow the instructions to use the device
34	医疗设备是移动的还是便携式的? Is the medical device intended to be mobile or portable?	器械是便携式的 Is portable
35	器械的使用是否取决于基本性能 Does the use of the medical device depend on essential performance?	N/A
36	Does the medical device have a degree of autonomy?	N/A
37	Does the medical device produce an output that is used as an input in determining clinical action?	N/A

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	分类 class	Risk Analysis 危害形成因素及可能后果 Factors & Consequences			S	P	RL		S	P	RL		S	P	RL
1. 能量危害 Energy Hazards															
1.0	Acoustic energy — infrasound — sound pressure — ultrasonic	N/A													
2.0	Electric energy	N/A													
2.1	Electric fields	N/A													
2.2	Leakage current — earth leakage — enclosure leakage	N/A													
2.3	Magnetic fields	N/A													
2.4	Static discharge	N/A													
2.5	Voltage	N/A													
3.0	Mechanical energy	N/A													
3.1	Kinetic energy — falling objects — high pressure fluid injection — moving parts — vibrating parts	N/A													
4.0	Potential (stored) energy	N/A													
4.1	— bending — compression — cutting, shearing — gravitational pull — suspended mass — tension — torsion	N/A													
5.0	Radiation energy	N/A													
5.1	Ionizing radiation — accelerated particles (alpha	N/A													

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	particles, electrons, protons, neutrons) — gamma — x-ray														
5.2	Non-ionizing radiation — infrared — laser — microwave — ultraviolet	N/A													
6.0	Thermal energy	N/A													
6.1	Cryogenic effects	N/A													
6.2	Hyperthermic effects	N/A													
2. 生物危害和化学品危害 Biological and chemical hazards															
1.0 生物 Biological agents															
1.1	细菌 Bacteria	如果细菌含量太高，可能会引起皮肤过敏 If the bacteria contents are too high, it may result skin allergy.	污染的生产环境和不清洁的个人卫生 Contaminated production environment & unclean personnel hygiene	1. 控制生产环境 Control production environment. 2.控制接触产品的工人的卫生 Control the hygiene of workers who contact the products.	S 2	P 5	Acc	低风险可接受不需要纠正措施 Low risk, it is acceptable, and no CA is required.	-	-	-		-	-	-
1.2	Fungi	N/A													
1.3	Parasites	N/A													
1.4	Prions	N/A													
1.5	Toxins	N/A													
1.6	Viruses	N/A													
2.0	**Chemical agents**	N/A													
2.1	Carcinogenic, mutagenic, reproductive	N/A													
2.2	Caustic, corrosive — acidic	N/A													

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	— alkaline — oxidants														
2.3	Flammable, combustible, explosive	N/A													
2.4	Fumes, vapors	N/A													
2.5	Osmotic	N/A													
2.6	Particles (including micro- and nano-particles)	N/A													
2.7	Pyrogenic	N/A													
2.8	Solvents	N/A													
2.9	Toxic— asbestos — heavy metals — inorganic toxicants — organic toxicants — silica	N/A													
3.0	Immunological agents	N/A													
3.1	Allergenic — antiseptic substances — latex	N/A													
3.2	Immunosuppressive	N/A													
3.3	Irritants — cleaning residues	可能会引起皮肤刺激 May cause irritation.	可能使用了危害材料 Hazardous materials may be used	1. 使用安全的材料 Use safe raw materials. 2. 过程中控制接触 Control contact in the process.	S 2	P 5	acc	低风险可接受不需要纠正措施 Low risk, it is acceptable, and no CA is required.	-	-	-	参见材料的 MSDS 以及手套的生物兼容性报告 Refer to material's MSDS and Biocompati-bility Testing Report of	-	-	-

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	分类 class	Risk Analysis 危害形成因素及可能后果 Factors & Consequences			S	P	RL		S	P	RL		S	P	RL
												gloves.			
3.4	Sensitizing	可能会引起皮肤过敏 May cause skin sensitization	可能使用了危害材料 Hazardous materials may be used	1. 使用安全的材料 Use safe raw materials. 2. 过程中控制接触 Control contact in the process.	S 2	P 5	acc	低风险可接受不需要纠正措施 Low risk, it is acceptable, and no CA is required.	-	-	-	参见材料的 MSDS 以及手套的生物兼容性报告 Refer to material‘s MSDS and Biocompati-bility Testing Report of gloves.	-	-	-
3. **Performance-related hazards**															
1.0	Data	N/A													
1.1	— access — availability — confidentiality — transfer — integrity	N/A													
2.0	Delivery	N/A													
2.1	— quantity — rate	N/A													
3.0	Diagnostic information	N/A													
3.1	— examination result — image artefacts — image orientation — image resolution — patient identity / information	N/A													
4.0	Functionality	N/A													

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	分类 class	Risk Analysis 危害形成因素及可能后果 Factors & Consequences			S	P	RL		S	P	RL		S	P	RL
4.1	— alarm — critical performance — measurement	N/A													
4.事件和情形 events and circumstances															
1.0	**Requirements**														
1.1	Inadequate specification of design parameters	N/A													
1.2	Inadequate specification of operating parameters	如果操作参数规范不充分，生产的产品可能不符合要求，如果有针孔，老化前后拉力强度和伸长率不符合要求可能会产生风险 If the specification of operating parameters is inadequate, the products produced may not conform to requirements, and it will result risk if pinhole, tensile strength and elongation of before aging and after aging did not conform to the specification.	操作参数规定不充分 Inadequate specification of operating parameters	1、严格按相关过程控制文件进行操作 2、按规定的频率监督检查生产过程和产品以确保符合所有规范要求 3、培训相关人员 1. Operate strictly as per relevant process control documents. 2. Supervise and inspect the production process and products as per the frequency required to ensure all specifications conform to ASTM requirements. 3. Train relevant operators	S 2	P 5	AC C	低风险可接受不需要纠正措施 Low risk, it is acceptable, and no CA is required.	-	-	-	1、配料文件 2、生产文件 3、包装文件 4、过程检查指导书 5、针孔测试记录表 6、物性测试记录表 1. Compounding Documents 2. Production Documents 3. Packing Documents 4. Process Check Instruction 5. Water Leakage Testing record 6. Physical Property Testing			

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												Record			
1.3	Inadequate specification of performance requirements	如果性能要求规定不充分，产品可能不符合要求，如果有针孔，老化前后拉力强度和伸长率不符合要求可能会产生风险 If specification of performance requirement is inadequate, the products produced may not conform to requirements, and it will result risk if pinhole, tensile strength and elongation of before aging and after aging did not conform to the specification.	操作人员不了解正确的性能要求 Operators did not know specification of performance requirements	1、严格按相关过程控制文件进行操作 2、按规定的频率监督检查生产过程和产品以确保符合所有规范要求 3、培训相关人员 1. Operate strictly as per relevant process control documents. 2. Supervise and inspect the production process and products as per the frequency required to ensure all specifications conform to ASTM requirements. 3. Train relevant operators	S 2	P 5	AC C	低风险可接受不需要纠正措施 Low risk, it is acceptable, and no CA is required.	-	-	-	1、配料文件 2、生产文件 3、包装文件 4、过程检查指导书 5、针孔测试记录表 6、物性测试记录表 1. Compounding Documents 2. Production Documents 3. Packing Documents 4. Process Check Instruction 5. Water Leakage Testing record 6. Physical Property Testing Record			
1.4	Inadequate specification of in-service requirements (e.g. maintenance, reprocessing)	N/A													
1.5	Inadequate specification of end of	如果产品过期仍使用，则可	寿命没有被清楚标	内盒标签上清楚标识生	S 1	P 6	AC C	低风险可接受不	-	-	-	内盒标签 Label of the	-	-	-

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	life	能会降低防护功能 If the products were used after its shelf life, the protection function may be reduced.	识和遵从 The shelf life is not clearly identified and followed.	产日期和有效期来提醒使用者在有效期内使用 Identify clearly on the label of the inner box about the manufacturing date and expire date to remind the user for use within its shelf life.				需要纠正措施 Low risk, it is acceptable, and no CA is required.				inner box.			
2.0 生产过程 Manufacturing process															
2.1	生产过程的不充分的控制 Insufficient control of manufacturing processes	如果生产过程没有充分控制，产品可能不符合要求，如果有针孔，老化前后拉力强度和伸长率不符合要求可能会产生风险 If the production process did not controlled sufficiently, the products produced may not conform to requirements, and it will result risk if pinhole, tensile strength and elongation of before aging and after aging did not conform to the specification.	操作人员不正确的操作 Improper operation of the operators	1、严格按相关过程控制文件进行操作 2、按规定的频率监督检查生产过程和产品以确保符合所有规范要求 3、培训相关人员 1. Operate strictly as per relevant process control documents. 2. Supervise and inspect the production process and products as per the frequency required to ensure all specifications conform to ASTM requirements. 3. Train relevant operators	S 2	P 5	AC C	低风险可接受不需要纠正措施 Low risk, it is acceptable, and no CA is required.	-	-	-	1、配料文件 2、生产文件 3、包装文件 4、过程检查指导书 5、针孔测试记录表 6、物性测试记录表 1. Compounding Documents 2. Production Documents 3. Packing Documents 4. Process Check Instruction 5. Water Leakage Testing record 6. Physical			

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												Property Testing Record			
2.2	对生产过程变更的不适当控制 Insufficient control of changes to manufacturing processes	如果生产过程变更而没有充分的控制，则生产的产品可能会不符合要求 If the production process was changed without sufficient control, the products produced may not conform to requirements.	1、变更前变更过程没有进行确认 2、过程没有有效监控 3、员工不当操作 1. The change process was not validated before changes. 2. The process was not monitored effectively. 3. Poor operation of the workers.	1、如果生产过程发生改变，必须进行试验，由总经理评估批准后进行变更 2、根据现有文件严格检验过程和产品 3、当有相关变更时培训相关人员 1. Trial must be done if production process be changed, and the application for changes must be evaluated and approved by general manager. 2. Check and inspect the process and products strictly as per existing documents. 3. Train relevant operators when any changes taken place.	S 2	P 5	AC C	低风险可接受不需要纠正措施 Low risk, it is acceptable, and no CA is required.	-	-	-	1、参见变更控制作业指导书 2、过程检查操作作业指导书 3、生产确认 1.See “Change Control Operational Instruction” 2. Process Check Operational Instruction. 3. Production Validation	-	-	-
2.3	材料/材料相容性信息的不适当控制 Insufficient control of materials/ materials compatibility information	生产的产品不符合相应的要求 The products manufactured accordingly may not conform to requirements.	原材料的不正确使用 Incorrect using of raw materials	1、清楚识别原材料 2、控制配方 3、配料过程控制 1. Identify clearly raw materials 2. Control formulation 3. Compounding process control	S 2	P 5	AC C	低风险可接受不需要纠正措施 Low risk, it is acceptable, and no CA is required.	-	-	-	1. 配料操作作业指导书 2、验收作业指导书 3、配料过程检查作业指导书 4、配方确认和试验报告			

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												Compounding Operation Instruction 2. Receiving Operation Instruction 3. Compounding Process Check Instruction 4. Formulation Validation and trial report			
2.4	分包商的不适当控制 Insufficient control of subcontractors	N/A													
3.0 运输和存放 Transport and storage															
3.1 3.2 3.3	不适当包装 Inadequate packaging 污染或变质 Contamination or deterioration 不适当的环境条件 Inappropriate environmental conditions	物料可能会污染产品，例如坏盒或坏箱，不良密封，外箱不符合结构。会导致产品脏污或产生针孔 Packaging material may contaminate the products, such as damaged box or case, bad seal, nonconformity structure of outer case. It will result the product to be dirty or result pinholes.	物料不符合要求且工人没有小心操作 The packaging materials do not comply with requirements, and the workers do not operate carefully.	1、确保物料符合采购规范 2、加强物料的检查 3、控制装箱过程 4、加强员工培训 1. Ensure that packaging materials meet purchasing specification. 2. Enhance the check on packaging materials. 3. Control the encasing process. 4. Enhance training to the workers.	S2	P5	ACC	低风险可接受不需要纠正措施 Low risk, it is acceptable, and no CA is required.	-	-	-	1、物料采购指导书 2、物料检验标准书 3、装箱操作作业指导书和出入库操作指导书 1. Packaging Materials Purchasing Instruction 2. Packaging Materials	-	-	-

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#	危害 Hazard		Risk Evaluation;可能原因 Possible causes	风险减少措施 Implementation of the Risk Control Measures	风险等级 (before CA)			剩余风险分析 Evaluation of the residual risks	风险等级 (after CA)			验证结果 Verification of the risk control measures	引进新危害？NH		
	分类 class	Risk Analysis 危害形成因素及可能后果 Factors & Consequences			S	P	RL		S	P	RL		S	P	RL
												Inspection Standard 3. Encasing Operational Instruction			
4.0 环境因素 Environmental factors															
4.1	物理(如热、压力、时间)Physical (eg. Heat, pressure, time)	过热会加速老化器械并降低其寿命 Overheat will accelerate aging of the device and reduce its shelf life	仓库温度超过要求的范围，没有按使用指导进行操作 Warehouse temperature exceed required scope, and do not operate as per using instruction indicated on the packaging materials	1、控制仓库的温度和湿度并培训相关人员 2、包装上清楚地标识“将产品放置于阴凉干燥处”以提醒使用者。 1. Control temperature and humidity in the warehouse and training relevant personnel. 2. Identify clearly on the packaging that “Place product in a cool and dry place” so as to remind users.	S 2	P 5	AC C	低风险可接受不需要纠正措施 Low risk, it is acceptable, and no CA is required.	-	-	-	参见出入库作业指导书 Refer to In and Out Warehouse Operational Instruction.	-	-	-
4.2	化学（如腐蚀、降解、污染）Chemical factors (eg. Corrosions, degradation, contamination)	N/A													
4.3	电磁场（电磁干扰的磁化系数）Electromagnetic fields (eg. Susceptibility to electromagnetic disturbance)	N/A													

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4.4	不适当的电力供应 Inadequate supply of power	N/A													
4.5	不适当的冷却剂供应 Inadequate supply of coolant	N/A													
5.0 清洁、消毒和灭菌 Cleaning, disinfection and sterilization															
5.1	Lack of validated *procedures*	N/A													
5.2	Inadequate specification of requirements	N/A													
5.3	清洁、消毒和灭菌的不适当执行 Inadequate performance of cleaning, disinfection or sterilization	N/A													
6.0 处理和废弃 Disposal and scrapping															
6.1	没有提供信息或提供的信息不充分 No or inadequate information provided	N/A													
6.2	使用错误 Use error	N/A													
7.0 配方 Formulation															
7.1	生物降解 Biodegradation	N/A													
7.2	生物兼容性 Biocompatibility	可能会引起皮肤过敏或刺激 May cause skin sensitization or irritation.	可能使用了危害材料 Hazardous materials may be	1. 使用安全的材料 Use safe raw materials. 2. 过程中控制接触	S 2	P 5	acc	低风险可接受不需要纠正措施 Low risk, it is	-	-	-	参见材料的 MSDS 以及手套的生物兼容			

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	分类 class	Risk Analysis 危害形成因素及可能后果 Factors & Consequences			S	P	RL		S	P	RL		S	P	RL
			used	Control contact in the process.				acceptable, and no CA is required.				性报告 Refer to material's MSDS and Biocompati-bility Testing Report of gloves.			
7.3	没有提供信息或提供的信息不充分 No information or inadequate specification provided	N/A													
7.4	不正确的配方 Incorrect formulations	N/A													
7.5	使用错误 Use error	N/A													
8.0 Usability															
8.1	易误解的或丢失的使用指导 Confusing or missing instruction for use	N/A													
8.2	复杂的或易误解的控制系统 Complex or confusing control system	N/A													
8.3	含糊的或不清楚的器械状态 Ambiguous or unclear	N/A													

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	分类 class	Risk Analysis 危害形成因素及可能后果 Factors & Consequences			S	P	RL		S	P	RL		S	P	RL
	state of the *medical device*														
8.4	含糊的或不清楚的设置、测量和其他信息展示 Ambiguous or unclear presentation of settings, measurements or other information	N/A													
8.5	结果的错误显示 Misrepresentation of results	N/A													
8.6	不充分的可见度、可闻度或触感 Insufficient visibility, audibility or tactility	N/A													
8.7	措施控制或实际状态展示信息的不良制图 Poor mapping of controls to actions, or of displayed information to actual state	N/A													
8.8	和现有设备比较的争论模式或制图 Controversial modes or mapping as compared to existing equipment	N/A													
8.9	由无经验或未经培训	N/A													

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	的人使用 Use by unskilled/untrained personnel														
8.10	不充分的副作用警告 Insufficient warning of side effects	N/A													
8.11	和一次性使用医疗器械被再次使用相关的不充分的危害警告 Inadequate warning of *hazards* associated with re-use of single-use *medical devices*	如果重复性使用一次性使用器械，则会降低其防护功能 If reuse the single use devices, the protection function will be reduced	没有按产品包装上的一次性使用说明操作 Not operate as per indication for single use on the packaging of the product	在包装标签和指导中标明一次性使用来提醒使用者 On the packaging materials label and instruction to identify “For Single Use” clearly to remind users	S 2	P 5	AC C	低风险可接受不需要纠正措施 Low risk, it is acceptable, and no CA is required.	-	-	-	参见内盒上的产品使用指导书或标识 Refer to “Product Using Instruction” or Label of the inner box.	-	-	-
8.12	不正确的测量和其他度量方面 Incorrect measurement and other metrological aspects	N/A													
8.13	和消耗品/附件/其他医疗器械不相容 Incompatibility with consumables/ accessories/ other medical devices	N/A													
8.14	Incorrect patient identification	N/A													
8.15	失误、犯错或错误	N/A													

Product Risk Management

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	Slips, laps and mistakes														
9.0 Functionality															
9.1	电子/机械完整性的非预期丢失 loss of electrical or mechanical integrity	N/A													
9.2	由于老化、磨损和重复使用造成的功能变质 Deterioration in performance (e.g. gradual occlusion of fluid or gas path, change in resistance to flow, electrical conductivity) as result of ageing, wear and repeated use	如果有针孔，拉力强度和伸长率不符合标准要求，会有风险 It will result risk if pinhole, tensile strength and elongation of before aging and after aging did not conform to the specification.	1、生产过程控制不好 2、没有严格按包装上的指导使用器械 1. Poor control to the production process 2. Not use the device strictly as per the indications showed on the packaging materials	1、严格控制生产过程从而确保产品符合ASTM 要求。 2、在包装上清楚地标识清楚“一次性使用”放置于阴凉干燥处”从而提醒使用者。 1. Strictly control production process so as to ensure the products manufactured meet ASTM requirements. 2. Identify clearly on the packaging materials “For single use” only, and “place the product in a cool and dry place” so as to remind users	S 2	P 5	AC C	低风险可接受不需要纠正措施 Low risk, it is acceptable, and no CA is required.	-	-	-	1、针孔测试记录 2、物性测试记录 3、产品标签 1. Water Leakage Testing record 2. Physical Property Testing Record 3. Product Labeling	-	-	-
9.3	疲劳失败 Failure of a component due to ageing, wear or fatigue	N/A													
10.0 Security															
10.1	Unsecured data ports	N/A													

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	that are externally accessible (e.g. network, serial or USB ports)														
10.2	Data without encryption	N/A							-	-	-		-	-	-
10.3	Software vulnerabilities that can be exploited	N/A													
10.4	Software updates without authenticity confirmation	N/A													

Completeness of risk control
We have reviewed the risk control activities to ensure that the risks from all identified hazardous situations have been considered and all risk control activities are completed.

Evaluation of overall residual risk

在对所有的风险控制措施已经实施并验证后，本产品造成的剩余风险都是可以接受的，达到可接受水平.
After all risk control actions are implemented and verified, the residual risks caused by this product are acceptable.

风险管理经验的评审：Review of risk management experience:
通过风险管理的评审，一次性使用丁腈检查用手套是低风险一次性使用医疗器械。只要使用者注意内盒上规定的信息并遵从它，他们就会安全地使用手套且不会对使用者造成危害。
By review of risk management, disposable nitrile examination gloves are the very low risk single-use medical device. As long as the users notice the information that is defined on the inner box and follow with it, thus they can use the gloves safely and won't cause risk to users.

Production and *post-production* activities
We actively collect and review information relevant to the *gloves* in the production and *post-production* phases. Including:
a) generated during production and monitoring of the production *process*;
b) information generated by the user;
c) information generated by the supply chain;
d) publicly available information; and
e) information related to the generally acknowledged *state of the art*.
Also considered the need to actively collect and review publicly available information about similar gloves and similar other products on the market.

Risk Analysis

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缩略词：Abbreviations used

RE	风险评估 Risk Evaluation
S	严重程度 Severity (S1-可忽略的 negligible，S2-边际的 marginal，S3-致命的 critical，S4-灾难性的 catastrophic)
P	危害发生概率 Possibility（P1-经常发生 frequent，P2-有时发生 probable，P3-偶然发生 occasional，P4-很少发生 remote，P5-极少发生 unlikely，P6-难以置信 incredible）
RL	风险等级 Risk Level = 严重程度 Severity × 危害发生概率 Possibility
RRM	风险减少措施 Risk Reduction Measure
NH	新危害发生 New hazard generated (no/ yes - if yes, 如不可接受，写出危害号码 then number of new hazard indicated)

风险等级评价准则 (Risk Evaluation Criteria):

发生概率 Possibility	严重度 Severity			
	S1	S2	S3	S4
P1	AFAP	N/ACC	N/ACC	N/ACC
P2	AFAP	AFAP	N/ACC	N/ACC
P3	AFAP	AFAP	AFAP	N/ACC
P4	ACC	AFAP	AFAP	AFAP
P5	ACC	ACC	AFAP	AFAP
P6	ACC	ACC	ACC	ACC

（N/ACC－不可接受区；ACC－可接受区；AFAP 尽可能低水平区）

采取措施后，全部剩余风险必须控制在 ACC 水平。
All residual risks must be controlled within acceptable level (ACC) after taking actions.
采取措施后的全部剩余风险，不允许有 N/ACC 水平的风险存在。
Concerning the residual risks after taking actions, it is forbidden to have risks at N/ACC level existed.