

CERTIFICATE OF CONFORMANCE

Certificate No: 2163 - PPE - 684/01

Respiratory protective devices, filtering half masks to protect against particles manufactured by
SHANDONG ZEDA MEDICAL PRODUCTS CO., LTD.
Yaojia Village, Zaoyuan Town, Lianhua District, Linyi City, Shandong Province, China
Continues to fulfil the requirements of

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2), This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation.

Product Definition		EU Type Examination Certificate		
Model	Class	Serial No.	Date	Issuing NB No.
		SURJE K1210	FFP2	2163-PPE-684

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **20/05/2020** and will be valid for one year, until **19/05/2021** if the manufacturer makes no major change to the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.




Sait KACMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code



EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163 - PPE - 684

Respiratory protective devices, filtering half masks to protect against particles manufactured by
SHANDONG ZEDA MEDICAL PRODUCTS CO., LTD.
Yaojia Village, Zaoyuan Town, Lianhua District, Linyi City, Shandong Province, China
are tested and evaluated according to

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation.

Product Definition

Brand Name: SURJE Model: K1210
Filtering half mask
Total Inwards Leakage Class - FFP2 NR

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.**
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective Equipment Regulation (EU) 2016/425 and harmonised standards, ensured by assessments based on **Annex 7 (Module C2)** or **Annex 8 (Module B)** of the regulation no later than 1 year from the beginning of serial production.

This certificate is initially issued on **20 / 05 / 2020** and will be valid for 5 years, if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.




Sait KACMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR code



Report

STFWT20207337

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Product Name	Protective mask	Specification Type	—
		Trademark	—
Trust Unit	Shandong Zeda Medical Products Co., Ltd	Tel	15295213038
Manufacturer	Shandong Zeda Medical Products Co., Ltd	Sample Grade	—
Sample Quantity	70 pcs	Sample Receiving Date	2020-04-01
Test Category	Entrusted inspection	Serial Number	—
Samples Conditions	Meet the testing requirements		
Document and Decide Accordance	EN 149: 2001+A1: 2009 (Respiratory protective devices -Filtering half masks to protect against particles-Requirements, testing, marking)		
Test Conclusion	The samples were tested, the items tested meet the requirements of EN 149:2001+A1:2009 standard for FFP2 level. Signature Date: 2020-05-14		
Remarks	The head harness of the mask provided by the applicant is ear hanging. Compatibility with skin is not recognized by the center. The test data are only for reference. The sample is not marked for reuse and does not require testing for blocking performance. The test conclusion of this report is only for the items inspected and does not mean that the uninspected items or functions meet the requirements. The results apply to the sample as received.		

Approver

陈敏

Examiner

杨森

Major tester

凌青梅



JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS.

检验检测报告

Test Report

STFWT20207337

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产品名称 Product Name	防护用品	规格型号 Specification Type	—
		商标 Trademark	—
委托单位 Trust Unit	山东泽达医疗用品有限公司	电话 Tel	15295213038
生产单位 Manufacturer	山东泽达医疗用品有限公司	样品等级 Sample Grade	FFP2
样品数量 Sample Quantity	70 只	送样日期 Sample Receiving Date	2020-04-01
检验检测类别 Test Category	委托送样检验	批号/货号 Serial Number	—
样品状态 Samples Conditions	符合检测要求		
检验检测及判定依据 Document and Decide Accordance	EN 149: 2001+A1: 2009 (Respiratory protective devices -Filtering half masks to protect against particles-Requirements, testing, marking)		
检验检测结论 Test Conclusion	样品经检验, 所检项目符合 EN 149: 2001+A1: 2009 标准规定的 FFP2 级要求。 签发日期: 2020-05-14 Signature Date		
备注 Remarks	皮肤相容性项目不在本中心认可范围内, 检测数据仅作参考 客户提供的口罩样品头带为耳挂式 样品未标记作为重复使用设计, 未要求测试阻菌性能 本报告检验结论仅对所检项目得出, 不代表未经检验的项目或功能符合要求。 本报告仅对来样负责。		

批准:
Approver

陈敏

审核:
Examiner

杨森

主检:
Major tester

凌青梅



JIANGSU QUALITY SUPERVISION AND INSPECTION CENTER FOR SPECIAL SAFETY PROTECTION PRODUCTS.

Test Report

检验检测报告

Test Report

STFWT20207340

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Product Name	Protective Mask	Specification Type	—
		Trademark	—
Trust Unit	Shandong Zeda Medical Products Co., Ltd	Tel	15295213038
Manufacturer	Shandong Zeda Medical Products Co., Ltd	Sample Grade	KN95
Sample Quantity	50 pcs	Sample Receiving Date	2020-04-01
Test Category	Entrusted Inspection	Serial Number	—
Samples Conditions	Meet the testing requirements		
Document and Decide Accordance	GB 2626-2006 《Respiratory protective equipment-Non-powered air-purifying particle respirator》		
Test Conclusion	The samples were tested, the items tested meet the requirements of GB 2626-2006 standard for KN95 level. SignaturDate: 2020-04-09		
Remarks	The test item marked "—" means that no single evaluation or no single evaluation conditions are met. The test conclusion of this report is only for the items inspected and does not mean that the uninspected items or functions meet the requirements. This report is responsible for samples only.		

Approver

陈敏

Examiner

吴高言

Major tester

蔡燕文

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产品名称 Product Name	防护用品	规格型号 Specification Type	—
		商 标 Trademark	—
委托单位 Trust Unit	山东泽达医疗用品有限公司	电 话 Tel	15295213038
生产单位 Manufacturer	山东泽达医疗用品有限公司	样品等级 Sample Grade	KN95
样品数量 Sample Quantity	50 只	送样日期 Sample Receiving Date	2020-04-01
检验检测类别 Test Category	委托送样检验	批号/货号 Serial Number	—
样品状态 Samples Conditions	符合检测要求		
检验检测及判定依据 Document and Decide Accordance	GB 2626-2006 《呼吸防护用品 自吸过滤式防颗粒物呼吸器》		
检验检测结论 Test Conclusion	样品经检验，所检项目符合 GB 2626-2006 标准规定的 KN95 级要求。 签发日期: 2020-04-09 SignaturDate		
备注 Remarks	标记“—”的检测项目表示不予单项评价或不具备单项评价条件。本报告检验结论仅对所检项目得出，不代表未经检验的项目或功能符合要求。本报告仅对来样负责。		

批准:
Approver


陈敏

审核:
Examiner

吴高言

主 检:
Major tester

蔡燕文



FFP2 NR
EN149:2001+A1:2009
CE 2163 K1210







FFP2 NR
EN149:2001+AL:2009
CE 2163 R1210