

CERTIFICACIONES

International Certification Registrar - International Certification Registrar



Certificate

No. ICR Polska/M6007045



Name and address of certificate owner:
Zhejiang Shaohua Medical Equipment Co., LTD
West floor 1, Building 2, BeiYuan science park, 968 Xuefeng west road, BeiYuan street, Yiwu city, Zhejiang province

Name and address of manufacturer:
Zhejiang Shaohua Medical Equipment Co., LTD
West floor 1, Building 2, BeiYuan science park, 968 Xuefeng west road, BeiYuan street, Yiwu city, Zhejiang province

Product name:
KN95

Product types:
SH-ZK12

This certificate confirms that the product meets the requirements of the following standards and within limits of its standards gives presumption of conformity with essential requirements of Regulation (EU) 2016/425.
EN 149:2001+A1:2009

The certification process has been carried out in accordance with the program PC-P-07-07. Evaluation has been carried out in accordance with test reports made by Shanghai MICEZ Equipment Testing & Technical Co., LTD Laboratory.

No. of test reports: MICEZ-2005-03275-PPE

Certificate issue date: 20.03.2020

Expiration date: 19.03.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-0127.

This certificate applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standards.



Director: Rafal Kalinowski

Warsaw, 20.03.2020

ICR Polska Co. Ltd.
ul. Plac Przymierza 6, 03-944 Warszawa
www.icrpolska.com, e-mail: icrpolska@icrp.com



Fiscal Year 2020
CERTIFICATION OF REGISTRATION

This certifies that:

ZHEJIANG SHAOHUA MEDICAL EQUIPMENT CO., LTD
West floor 1, building 2, BeiYuan Science Park, No. 968, Xuefeng West Road, BeiYuan street, Yiwu City, ZHEJIANG, 322000, CHINA

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

HEALREG SERVICE INC

Owner/Operator Number: 10066235
Device Listing#: See annex

HEALREG SERVICE INC will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. HEALREG SERVICE INC makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. HEALREG SERVICE INC assumes no liability to any person or entity in connection with the foregoing. Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. HEALREG SERVICE INC is not affiliated with the U.S. Food and Drug Administration.

Chief engineer
 Issued: April 1, 2020
 Expiration Date: December 31, 2020



5 CAPAS DE PROTECCIÓN



EFICIENCIA DE FILTRACIÓN



CAJA CONTIENE 10 UNIDADES