Technical Documentation Review Report

No. HKTDR2020071100

Date: 27 Jul 2020

Xiantao Zhengxin Nonwoven Products CO., LTD
Pengzhao Road, Pengchang Town, Xiantao City, Hubei Province, China
The documentation was submitted by the client for the product as: **Medical face mask(non-sterile)**

SGS Job No.	:	GZHL2007036960MD
Model/Type	:	ZX234
Manufacturer	:	Xiantao Zhengxin Nonwoven Products CO., LTD
Address of Manufacturer	:	Pengzhao Road, Pengchang Town, Xiantao City, Hubei Province, China
Country of Origin	:	CHINA
Country of Destination	:	Europe
Date of Documentation Received	:	27 Jul 2020
Review Period	:	27 Jul 2020 - 31 Jul 2020
Service Requested	:	Review the completeness of the Technical Documentation in accordance with the requirements of Annex VII of COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices and its amendments as well as relevant harmonized standards.
Review Summary	:	Based on the submitted documentation, this is to conclude that non-compliance or missing information was not identified according to the requirements of Annex VII of COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices and its amendments as well as relevant harmonized standards. Please note that no sample is provided for review and no testing is carried out in this service.
Date of Expiry	:	30 Jul 2021 (1 year)

DISCLAIMER - PLEASE READ

While all due care and skill were exercised in carrying out this review, SGS Hong Kong Ltd.(SGS) accepts responsibility only for proven gross negligence. Considering that the situation surrounding COVID-19 is evolving, the findings provided in this report may change on a daily basis. This report relates only to the submitted documentation. The authenticity of the documentation reviewed by SGS, and the consistency of the product and the documentation is not covered. Conformance to all the regulatory requirements is the sole responsibility of the manufacturer including the production and quality control of the product(s). This report is not a legal document and cannot be used as such. This is not a legal interpretation of the law. Reliance should be placed on the wording of the legislation itself. SGS may have extracted from the compiled data specific criteria which are not intended to be the substitute of the relevant legislation and/or standards.

Signed for and on behalf of
SGS Hong Kong Ltd

Ivan CHAN
Vice President – R & D and Innovation

Additional comments

According to Article 9 and Annex IX of COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices, Medical face mask(non-sterile) (ZX234) according to EN14683:2019+AC:2019 "Medical face masks - Requirements and test methods" is considered as class 1 medical device.

According to Article 11 of the directive, conformity procedure as stated in Annex VII of the directive shall be followed.

According to Announcement No.12 (2020) of the Ministry of Commerce, People's Republic of China, as of April 26, 2020, exporting companies of SARS-CoV-2 testing reagents, medical face masks, medical protective suits, ventilators and infrared thermometers that have obtained certification or authorization from other countries shall submit an Export Declaration of Medical Supplies in writing together with customs declarations, as a warranty that the products are compliant with the quality standards and safety requirements of the importing countries (regions).

*** End of Report ***