

CE Technical Documentation Review Report

Applicant: Xinxiang Huaxi Sanitary Materials Co., Ltd.

Dingluan Industrial Zone Changyuan, Xinxiang, 453400 Henan, China

Report Number: 60362251-001

Examination intent: Examination the completeness of the Technical

Documentation according to the requirements of

REGULATION (EU) 2017/745, Annex II

Product(s): Disposable Surgical Face Masks

Type(s)/Model(s): Type IIR

Classification: Class I

(according to manufacturer's declaration)

Examination period: Mar.27.2020

Date of expiry: Mar.26.2025

Review result: During the examination of the provided Technical

Documentation (No.: HX-JS-CE-04, Version A/0, Dated 2020-Mar-26), no Non-compliance according to the requirements of REGULATION (EU) 2017/745,

Annex II was detected.

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Vice General Manager Medical Greater China

TÜV Rheinland (China) Ltd.

We hereby declare that in accordance with the contents of CE Technical Documentation Review Report, the assessments carried out are the voluntary nature based on applicant request and are not equivalent to the mandatory conformity assessment procedures carried out by TÜV Rheinland LGA Products GmbH, Notified Body 0197 to the aforementioned Regulation.

To verify the report validity, please send email to: service-gc@tuv.com