

## CE Technical Documentation Review Report

**Applicant:** **Shandong Shangwei Medical Products Co., Ltd.**  
North of Fumin Avenue East Section,  
Qinghe Sub-district Office, Cao County,  
Heze City, 274400, Shandong Province, China

**Report Number:** 60366567-001

**Examination intent:** Examination the completeness of the Technical Documentation according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII

**Product(s):** Examination Vinyl Gloves

**Type(s)/Model(s):** Powder- free  
(Size: S, M, L, XL)

**Classification:** Class I  
(according to manufacturer's declaration)

**Examination period:** Apr.24.2020

**Date of expiry:** May.26.2024

**Review result:** During the examination of the provided Technical Documentation (No.: SWCE-01, Revision: A/1, Dated 2018-12-06), no Non-compliance according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII was detected.

  
  
Yuhong CHE  
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 Directive.*

**To verify the report validity, please send email to: [service-gc@tuv.com](mailto:service-gc@tuv.com)**