

CE Technical Documentation Review Report

Applicant:

Zhonghong Pulin Medical Products Co.,Ltd.

West Industrial Park, Luannan County, Tangshan

City, 063500, Hebei, China

Report Number:

50149149-001

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):

Powder-free Nitrile Examination Gloves

Type(s)/Model(s):

XS,S,M,L,XL

Classification:

Class I

(according to manufacturer's declaration)

Examination period:

Jun.21.2018

Date of expiry:

Jun.20.2023

Review result:

During the examination of the provided Technical Documentation (No.: TS-02, Revision: A2, dated 2018-04-10), no Non-compliance according to the requirements of the Medical Devices Directive

93/42/EEC Annex VII was detected.

TÜV Rheinland (China) Ltd.

Yuhong Manage

Medical Services

Rev.01, 2002-10-10