

23rd July 2020**Handan HY FFP3 Filtering Half Masks****1. Manufacturer Information**

Handan Hengyong Protective & Clean Products Co., Ltd (Handan HY) is a manufacturer of PPE - filtration media, respirators and coveralls. Optimum Medical is currently working closely with Handan HY in order to supply FFP3 Filtering Half Masks to Europe.

2. Product and Certification Information

Handan HY hold Quality Management System certification ISO 9001 which has been granted by Notified Body, SGS, for the design and manufacture of various items of PPE including filtration media and particulate respirators.

They also hold CE certification for various models of FFP1, FFP2 and FFP3 granted by British Standards Institution (BSI). The purpose of the CE certificate is to confirm that all products listed on the certificate meet the requirements of EN 149:2001 + A1:2009. There are 20+ models listed on the certificate (ref CE 690991) including all models being imported by Optimum Medical:

- Model A HY9632
- Model B HY8632
- Model C HY8932
- Model D HY9332

The certificate states that “BSI have carried out the relevant Type Examination procedures under the requirements with the Regulation (EU) 2016/425 of the European Parliament and Council relating to Personal Protective Equipment Regulation (PPE) Annex V (Module B) and meets the relevant health and safety requirements specified in Annex II.”

Handan HY have provided us with multiple test reports including reports issued by BSI to EN 149:2001+A1:2009 (Report no. 8521713 and 8027610). In this test report, the samples used are from Model B HY8632 and another Handan HY model HY8232 that we are not currently importing. All requirements of the standard were met.

Handan HY have also provided us with test reports dated 2007 for the Model A HY9632 and Model C HY8932 issued by BSI to EN 149:2001 (Report no. 255/7010537 and no. 255/7007591) and have further testing available at request. All requirements of the standard were met.

BSI have issued their current CE certificate (ref CE 690991) based on the testing above and have determined that requirements for ALL 20+ models now meet EN 149:2001+A1:2009.

Signed:



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Product Manager

