

Documentation No.	TCF.01 Appendix 1	<b>HEMU (Shandong) Medical Instrument Technology Co., Ltd</b> <b>Technical File of EU Type Examination Certification</b>
Creation Date	22.04.2020	
Revision No.	00	
Revision Date		

## 8. DECLARATION OF CONFORMITY

Manufacturer

Authorised Representative (if applicable)

Name HEMU (Shandong) Medical Instrument Technology Co., LTD.  
Address 3/F, C Area, Blue Venture Valley, Longhai Road East, Keji Road North, Nanhai New District, Weihai City, Shandong, China

Name To-Be confirmed  
Address To-Be confirmed

declares that the new PPE described hereafter

Product name and model KN95 Protective Mask and Modle N1

is in conformity with the provisions of Module B of the Regulation (EU) 2016/425 Personal Protective Equipment and with the national standard transposing harmonized standard (s):

- EN 149:2001 + A1:2009 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking
- EN 13274-7:2019 Penetration of Sodium Chloride /Penetration of Paraffin Oil
- EN 13274-3:2001 Breathing resistance
- EN 13274-4:2001 Flammability
- EN 13274-2:2019 Practical performance test
- EN 13274-1:2001 Total inward leakage
- EN 13274-6:2001 Temperature conditioning

It is subject to the procedure set out in Module C2 of Regulation (EU) 2016/425 Personal Protective Equipment under the supervision of the notified body UNIVERSAL CERTIFICATION AND SURVEILLANCE SERVICES TRADE CO., Necip Fazl Bulvari Keyap Sitesi E2 Blok, No. 44/84 Yukari Dudullu, 34775, Turkey. Notified Body No: 2163.

Done at Place , Date 22.04.2020

3/F, C Area, Blue Venture Valley, Longhai Road East, Keji Road North, Nanhai New District, Weihai City, Shandong, China

Name:  
On behalf of Company

