


EC Declaration of Conformity

According to the **REGULATION (EU) 2017/745 OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL**
Class I Medical Device (non-sterile)

On the basis of the referenced test report(s), sample(s) tested of the below product have been found to comply with the standards harmonized with the directives listed on this verification at the time the tests were carried out. Other standards and Directives may be relevant to the product. This verification is part of the full test report(s) and should be read in conjunction with it <them>.

Applicant Name:	SHANDONG XINGYU GLOVES CO.,LTD
Address:	MIDDLE YAOQIAN ROAD, CHAOYANG DISTRICT, GAOMI CITY, SHANDONG PROVINCE, P.R.CHINA
Product Description:	Disposable Mask
Models/Type References:	M001, M001-1
Brand Name(s):	
Standard(s)/Directive(s):	EN ISO 13485:2016 EN ISO 14971:2012 EN 1041:2008 EN ISO 15223-1:2012 EN ISO 10993-1:2009/AC:2010 EN ISO 10993-5:2009 EN ISO 10993-10:2013 EN 62366:2008 EN 14683:2019+AC:2019
Conformity assessment procedure:	EC Declaration of Conformity + Technical Documentation(Annex II) + Technical Documentation on Post-Market Surveillance (Annex III)
EC representative:	Share Info GmbH
Address:	Heerdter Lohweg 83, 40549 Düsseldorf

Singed on: 04 November.
Authorized by:

Place: Gaomi, Shandong, China



Signature

General manager: Xingyu Zhou
Place: Shandong, China
Date: Nov. 04, 2020