

XIANTAO CHENGUANG PROTECTION COMMODITY CO., LTD

GONGQING INDUSTRY GARDEN, YEWANG ROAD, XIANTAO CITY, HUBEI, CHINA

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EC DECLARATION OF CONFORMITY

Medical Device Directive (93/42/CEE)

Manufacturer

Name: Xiantao Chenguang Protection Commodity Co. Ltd

Address: Gongqing Industry Garden, Yewang Road, Xiantao City, Hubei China

EC- Representative

Name: Sungo Europe B.V.

Address: Olympisch Stadion 24, 1076 DE Amsterdam, Netherlande

Product:

Name: Non-woven face mask

Code: 20191017CG

Details:

medical disposable face mask with earloops, not sterile

Medical device Class I

Test information:

Laboratory: Nelson Laboratories, LLC.

Test Article: 20191017CG

Test report: 1235898-S01

We confirm the above product meets the requirements of Medical Device Directive (93/42/CEE).

Applied standards:

EN14683:2019

EN ISO 14971:2012

EN 1041:2008

EN ISO 10993-1:2010

EN ISO 10993-5:2009

EN ISO 10993-10:2013

The declaration is issued from manufacturer.

16/04/2020

