



EC Declaration of Conformity

Regarding Medical Device Regulation (EU)2017/745

Manufacturer:

Name: Anji Hongde Medical Products Co., Ltd
Address: Building No.1,3,4,5,Bamboo Industrial Zone,Xiaofeng Town,Anji County,Huzhou City,Zhejiang,P.R.C 313301

European Authorized Representative:

Name:SUNGO Europe B.V.
Address:Olympisch Stadion 24,1076DE Amsterdam,Netherlands

Product:

Name: Elastic Bandages

Model:

Natural white spandex plain elastic Bandage,cotton crepe elastic bandage,skin color cotton high elastic bandage,skin color high elastic bandage,bleached cotton crepe elastic bandage,natural white cotton plain elastic bandage,PBT medical elastic bandage,medical gauze bandage.

Specification and Size:width×length (fully extended length) (1-30cm)×(0.3-15m),Cotton woven bandage specifications:width×length (fully extended length) (1-50cm)×(0.3-150m) net elastic bandage:0.5#,1#,2#,3#,4#,5#,5.5#,5.8#,6#,7#,8#,9#,10#.

Classification: Class I

Rule: According to Rule 1, Annex VIII, Chapter III of EU Medical Device Regulation (EU)2017/745

Conformity assessment procedure: Annex II+III

We confirm our product can meet the requirement of Medical Device Regulation and the following harmonized standards:

EN ISO 13485:2016/EN ISO 14971:2012

EN ISO 15223-1:2016 / EN 1041:2008

ISO 10993-1:2018 / EN ISO 10993-5:2009 / EN ISO 10993-10:2018

*On behalf of SUNGO Europe office, I confirmed the
EU REP of the company who issue this document.*

Signature:

Date: 2020.3.19

Position:



Authorized Signature (S)

