



# EASYCAP

EEG Recording Caps and Related Products

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## Medical Disposable Masks, Pack of 10

Catalogue-Number 710005

Price EUR 6,60 (VAT and Shipping add on top)

CE Conformity Declaration next page, Test Report according EN 14683 (MDD) available upon request



File No: CE-TCF-002



**EC Declaration of Conformity**  
Regarding Medical Device Directive(93/42/EEC)  
including Directive 2007/47/EC



**Applicant**

Name: Shandong Zhushi Pharmaceutical Group Co., Ltd

Address: No.6 Shande Road,Shan County, Heze City, Shandong, China

**EC Representative**

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

**Product**

Name: Disposable Medical Face Mask (non-sterile)

Type: Length: 7cm ~ 24cm, Width:4cm ~ 20cm, or customized

**Classification**

Class I (MDD, Annex IX), Rule 1(All non-invasive devices are in class I)

SRN: -

UDI: -

**Conformity Assessment Route**

Annex VII

We confirm our product can meet the requirement of Medical Device Directive(93/42/EEC) and the following harmonized standards:

EN ISO 13485: 2016

EN ISO 14971: 2012

EN ISO 15223-1: 2016

EN 1041: 2013

EN ISO 10993-1: 2009/AC: 2010

EN ISO 10993-5: 2009

EN ISO 10993-10: 2013

EN 14683:2019

Signature

Date: 2020/04/20

Position



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