



DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745



Manufacturer:

Xiantao Fortune Medical Supplies Co., Ltd

Address:

No.182 Hechang New Street, Pengchang Town,
Xiantao City, Hubei Province, China

EC Representative:

SUNGO Europe B.V.

Address:

Olympisch Stadion 24, 1076DE Amsterdam,
Netherlands

Product Name:

Cap

Model:

18"/19"/20"/21" or Customized

SRN:

/

Basic UDI-DI:

/

Classification ☐

Class I

Rule:

Rule 1, Annex VIII, Regulation (EU) 2017/745

Conformity Assessment Procedure: Annex II+III of Regulation (EU) 2017/745

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the following harmonized standards.

EN ISO 14971: 2012

EN ISO 15223-1: 2016

EN 1041:2008+A1:2013

ISO 10993-1: 2018

EN ISO 10993-5: 2009

EN ISO 10993-10: 2013

Signature:

Name / Position: Du Dan / GM



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



Date: 2020.09.14

Authorized Signature (S)

Place: Hubei / China