



## Declaration of Conformity

### Regarding Medical Device Regulation(EU) 2017/745

#### Manufacturer

Name: Safeway Industry Healthcare

Address: No.106, Changan Road, Changshangkou, Xiantao, Hubei, China

#### European Authorised Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

#### Product

Name: Surgeon cap

Model: - with elastic , with ties , with absorption pad

SRN: - CN-MF-000001568

UDI-DI: - 6974601790110327

Classification: Class I

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

Conformity assessment procedure: Annex II+III

Safeway Industry Healthcare ,under the sole responsibility declares that our product meets the requirements of Medical Device Regulation (EU) 2017/745 and the following harmonized standards.

EN ISO 13485:2016

EN ISO 14971: 2012

EN ISO 15223-1: 2016

ISO 10993-1: 2018

EN ISO 10993-5: 2009

EN ISO 10993-10: 2013

EN 1041: 2008

EN 62366-1:2015

Signature: 蔡志敏

Position: Cai zhimin / General Manager

Date: July 14 , 2020

