



EC Declaration of Conformity



Regarding Medical Device Regulator(EU 2017/745)

Manufacturer

Name: Guangxi Ehall Medical Technology Co.,Ltd

Address: ROOM 6108, 6F KECHUAN BLGD, 25-1, KEYUAN ROAD NANNING,
GUANGXI, CHINA

EU Rep

Name: SUNGO CERT GmbH

Address: Lindenstraße 48-52, 40233 Düsseldorf,Germany

Product

Product Name: Silicone Cheek Retractor (REF030105)

Silicone Cheek Retractor (REF030106)

Silicone Cheek Retractor (REF030107)

Classification: Class I

Rule: According to Rule 1

We confirm our product can meet the requirement of Medical Device Regulator (EU 2017/745) and the following harmonized standards.

EN ISO 14971:2012

EN ISO 15223-1:2016

EN 1041:2008+A1:2013

EN ISO 10993-12009/AC:2010

EN ISO 10993-5:2009

EN ISO 10993-10:2013

EN ISO 13485:2016

Signature: 

Date: 2021.06.06

