

DECLARATION OF CONFORMITY

Regarding Medical Device Directive(93/42/EEC)
including Directive 2007/47/EC

Manufacturer: Hunan Chopard Medical Devices Co., Ltd

Address: 88 Tongxin Road, Longfu Town Industrect District, Liuyang City

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: Medical surgical mask (Non-sterile /Type IIR)

Specification:

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

Conformity Assessment: Annex VII



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

EN ISO 14971:2012

EN ISO 10993-5:2009

EN ISO 15223-1:2016

EN ISO 10993-10:2013

EN 1041:2013

EN 14683:2019

EN ISO 10993-1:2009/AC:2010

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

Signature: 

Date: 2020年8月7日





Authorized Signature (S)