



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

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

Applicable 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
EN 14683:2019+AC:2019

Remark

The declaration of conformity is valid in connection
with the release technical document
CE/MDR-LD-01-01.

All the supporting documentation is retained at the
premises of the manufacturer.

The Declaration of Conformity is exclusively under
the sole responsibility of the manufacturer.

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



Authorized Signature (S)

Manufacturer

Name: Shenzhen Lyttop Healthcare Limited
Address: A201, Building 7, Dongjiu Innovation and
Technology Park II, No.73, Xiali South Road, Xiali
Lang Community, Nanwan Street, Longgang District,
Shenzhen

Product Information

Name: Disposable Medical Face Mask
Model: LT0418, 17.5*9.5cm
GMDN: 35177
Basic UDI-DI: /
Classification: Class I

Declaration

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

Signature:

Date:

2020.12.17

Position:

General manager

Place:

Guangdong, China

