

EU DECLARATION OF CONFORMITY

Manufacturer

Name: Zhejiang Lanhine Medical Products Ltd.
Address: 1989 Cidong Road, Cidongbinhai District,
315300 Cixi City, Zhejiang Province, People's
Republic of China

Authorized Representative

Name: SUNGO Europe B.V.
Address: Olympish Stadion 24, 1076DE
Amsterdam, Netherlands

Model: 15603F(Lanhine code), 3ply face mask earloop, different colors
Mundschutz Tom (708 Band, Gummi und Motiv)

Model: 15703F(Lanhine code), 3ply face mask tie-on, different colors
Mundschutz peppler go (718 Band, Gummi und Motiv)

Basic UDI: 69715136815603FTJ, 69715136815703FTR.

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 following harmonized standards.**

ENISO14971:2012

EN1041:2008+A1:2013

EN ISO 10993-5:2009

EN 14683:2019+A1:2019

EN ISO15223-1:2016

ISO 10993-1:2018

EN ISO10993-10:2013

Place: Ninbo Zhejiang

Date: 2021-10-11


Gu Junfei 2021-10-11
Gu Junfei/QA Manager
On behalf of Zhejiang Lanhine Products Ltd.