



DECLARATION OF CONFORMITY
Regarding Medical Device Regulation (EU) 2017/745



Product Name: Disposable Medical Face Mask

Model: Ear Loop, 17.5*9.5cm

SRN: _____ / _____

Basic UDI-DI: _____ / _____

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 the following harmonized 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