EC DECLARATION OF CONFORMITY

DOC No: DES-DOC-002

Product Identification

Product name:

Disposable surgical mask

Brand Name:

Soomfree, Wells, Wellpure

Model Name:

Soomfree Health Face Mask (KF94) Wells Health Face Mask (KF94)

Wellpure Health Face Mask (KF94)

GMDN code:

57794

Manufacturer

Company name:

DES IND

Address:

444-38, Juseok-ro, Bibong-myeon, Hwaseong-si, Gyeonggi-do, Republic of

Korea

Authorized Representative

Company name:

Address:

Contact:

Conformity Assessment

Device classification:

Class I by rule 1 according to Annex IX of the MDD

Assessment Procedure:

Annex VII

Harmonized Standards:

attached 'Harmonized Standards List'

DES IND declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC Annex I essential requirement, as amended by MDD 2007/47/EC for Medical Device. All supporting documentation is retained at the promises of the manufacturer

Company Representative:

Title:

President

Date:

Oct. 8, 2020

Place:

444-38, Juseok-ro, Bibong-myeon, Hwaseong-si, Gyeonggi-do, Republic of

Korea

Signature:

Hongiun Chung

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