

## DECLARATION OF CONFORMITY

This Declaration of Conformity is issued under the sole responsibility of Medical Devices Technology International Limited. It conforms to ISO 13485:2016.

The product listed in the schedule is in conformity with Medical Device Regulation EU 2017/745 in respect of Class 1R products (pursuant to previously essential requirements against Annex VI of the Medical Devices Directive 93/42/EEC and the Medical Devices Regulations 2002 UK Statutory Instrument 2002 No. 618), and FDA Regulation No. 884.4530 510(k) Exempt Device Class 1 that provides for the issuing of an EU Declaration of Conformity:

### SCHEDULE

Product Name: Myaid® Medical Face Mask Type IIR  
Product Code: 4020  
EAN: 5060228630330  
FDA Product Code: QKR  
Test Standard : EN14683:2019

Indication for Use: Single user face mask, the device intended to be placed over the nose and mouth of medical personnel to prevent the transmission of airborne organisms during surgery or during patient examination. It is made of fabric material that enables the user to breathe normally through the mask and is held in place with flexible elasticated ear loops.

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Signed: *mlevermore* Date: 20/12/2020

Professor Martin Levermore MBE, Chief Executive Officer  
For & on behalf of: Medical Devices Technology International Ltd



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