

This Declaration of Conformity is issued under the sole responsibility of the manufacturer:
Portwest, IDA Industrial Park, Westport, Co Mayo, F28 FY88, Ireland. Reg No. 21284

Portwest declares that:

P030 - Medical Mask Type IIR -



the product referred to in this Declaration satisfies the essential safety and health requirements of the Medical Devices Regulation (EU) 2017/745 - and is tested to the following standards:

93/42/EEC (Class 1 Medical device) (1993)
EN 14683 TYPE IIR (2019)

Nelson Laboratories LLC
6280 S. Redwood Road, 84123, USA

TEST REPORT No.:

Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) - CN101/CN102/ZSFM21
Microbial Cleanliness (Bioburden)- CN101/CN102/ZSFM21
Synthetic Blood Penetration Resistance - CN101/CN102/ZSFM21

Signed for and on behalf of Portwest



Raymond Carney
Chief Operations Officer