



EU TYPE DECLARATION OF PRODUCT CONFORMITY

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:

P031 - Medical Mask Type IIR -



the product referred to in this Declaration satisfies the essential safety and health requirements of the Medical Device 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) - 366521
Differential Pressure (Delta P) - 3037-20 Rev.00
Microbial Cleanliness (Bioburden)- 3768-20 Rev.00
Synthetic Blood Penetration Resistance - 3969-20 Rev. 00

Signed for and on behalf of Portwest

Raymond Carney

Chief Operations Officer

Done at: Portwest, IDA Industrial Park, Westport, F28 FY88, Co. Mayo, Ireland on 07-Aug-2020

Manufacturing Site: CMT Equipment Ltd. - Trident Works, Mulberry Way, Belvedere, DA17 6AN, UK

Device registered to the UK Competent Authority (MHRA) - Application ref 2020061802182077