



## **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:

### **P029 - Medical Mask Type IIR Dispenser Box**



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) - 1341302-S01  
Differential Pressure (Delta P) - 1341300-S01  
Microbial Cleanliness (Bioburden)- 1341298-S01  
Synthetic Blood Penetration Resistance - 1341299-S01

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: Crown Name Disposable Hygiene Products Fty.,Ltd. Chengbei Industrial Zone, Xinzhou District, Wuhan, China - REF : CN102  
EC REP : Lotus NLB.V. Koningin Julianaplein 10, leVerd, 2595AA, The Hague, Netherlands.

Device registered to the Netherlands Competent Authority (CIBG - Ministerie van Volksgezondheid, Welzijn en Sport) - Application ref. NL-CA002-2019-47317