CEDeclaration of Conformity



This declaration of conformity is issued under the sole responsibility of the manufacturer:

Paulson Manufacturing Corporation

46752 Rainbow Canyon Road, Temecula, CA 92592, USA

and the authorized representative in the European Union, i.e.

Paulson International GmbH

Max-Holder-Str. 23, 60437 Frankfurt/Main, Germany

declare that the PPE described thereafter

IDC Products and Markings: See Attached List (List of Certificates of IDC Products)

are in conformity with the provisions of the Directive 2001/95/EC on general product safety and the PPE Regulation (EU) 2016/425 and, where such is the case, with the national standard transposing harmonized standard no.

EN 166:2001

partly applied, according to the specific requirements to protect against the SARS-CoV-2 Virus

and is identical to the PPE which is subject to

CE Type Certification Certificate No.: See Attached List (List of Certificates of IDC Products)

issued by ECS GmbH - European Certification Service, Huettfeldstrasse 50, 73430
Aalen, Germany, Notified Body 1883, as per
Module-B and is subject to the conformity assessment procedure set out in Module C as per PPE Regulation (EU) 2016/425.

According to Regulation (EU) 2017/745 on medical devices, Annex VIII, Clause 4.1 and 4.4 the product is assigned to a Medical Device of Class 1.

Done at Temecula, CA, USA, on this date _	B-19-22	
Brennen Johnson		
Management Representative ISO 9001-201	5	