



Declaration of Conformity



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

Hans Keim Kunststoffe GmbH
Im Lachengrund 45-47,
78658 Zimmern ob Rottweil,
Germany

declare that the PPE described thereafter

PlexyCap – Keim Protective Face Shield

is 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 of

CE Type Certification Certificate No.: C3006.1HKK,
(test reports 1179-ECS-20 / MR 11791-ECS-20

valid to 2021-05

issued by ECS GmbH, Huettfeldstrasse 50, 73430 Aalen, Germany
Eye Protection and Personal Protective Equipment 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 RREGULATION (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 Zimmern, Germany, on this date

Zimmern 26.05.2020

City, Date

Signature