

**EU Declaration of Conformity
PERSONAL PROTECTIVE EQUIPMENT
REGULATION (EU) 2016/425**

This declaration of conformity is issued under the sole responsibility of

PulseLavage AB
Rubanksgatan 8
74171 Knivsta
Sweden

Declares that the PPE unit described hereafter:

FaceGuard, Facial Splash Shield FGC-001 GTIN 07350093650587

Is in conformity with the provisions of Regulation (EU) 2016/425, including fulfilment of the applicable essential health and safety requirements set out in Annex II, and with applicable sections of EN 166:2001, and is identical to the PPE which is the subject of Category I: internal production control (module A) set out in Annex IV of the Regulation (EU) 2016/425).

Devises have been designed and manufactured under a quality management system, certified to ISO 13485:2016, Orion Registrar Inc, 7502 W. 80th Avenue, Suite 225, Arvada, Colorado 80003.

A copy of the Technical File and corresponding documentation of the devices can be obtained by contacting PulseLavage AB.

Date: Sweden April 2020



Magda Forsberg
Management Representative
PulseLavage AB