



Declaration of Conformity

Manufacturer: Tecman Speciality Materials Ltd

Berrington House, Berrington Rd, Royal Leamington Spa CV31 1NB, United Kingdom

Declare the product: Optec113 (purple Wipe clean bio headband with strap and impact resistant screen)

Optec123 (Washable blue bio headband with strap and impact resistant screen)

Notified body: SATRA Technology Europe Ltd (2777) - Notified Body responsible for EU type-

examination and Module C2 conformity assessment

EU type examination cert: 2777/18412-01/E00-00

Product description: Consisting of a bioplastic headband with closed cell foam padding, an adjustable

silicone strap, and a screen which snaps onto the headband, the Optec[™] 100 Series is a range of reusable face shields intended for use in healthcare environments. The face shield protects the wearer from droplets and splashes of infectious agents, stays comfortable and secure over a whole shift, and is more eco-friendly than competing products. The range includes two types of headbands and three types of

screens which can be used interchangeably.

The equipment is in conformity with the following directives:

REGULATION (EU) 2016/425 CAT III

Standards/Technical specifications applied:

EN 166: 2001 clauses 6.1 (General Construction), 6.2 (Materials), 6.3 (Headbands), 7.1.1 (Field of Vision), 7.1.2.1 (Refraction), 7.1.2.2 (Transmittance) 7.1.2.3 (Diffusion), 7.1.3 (Quality of Material and Surface), 7.1.4.2 (Increased Robustness), 7.1.5.1 (Thermal Stability), 7.1.5.2 (UV Resistance), 7.1.7 (Resistance to Ignition), 7.2.4 (Droplets and Splashes), and 7.3.2 (Resistance to Fogging).

And the equipment is in conformity with the following harmonised standards:

EN 166:2001

With the product markings:

Screens: TEC 1 S N (Manufacturer; Optical Class 1; Increased Robustness; Resistance to Fogging)
Headbands: TEC EN 166 3 S (Manufacturer; Standard; Field of Use: Liquids; Increased Robustness)

This declaration of conformity is issued under the exclusive responsibility of the manufacturer. Royal Leamington Spa, 14/04/2021

Kevin Porter

Tecman Speciality Materials

Technical Director