



## Declaration of Conformity

- Manufacturer:** Tecman Speciality Materials Ltd  
Berrington House, Berrington Rd, Royal Leamington Spa CV31 1NB, United Kingdom
- Declare the product:** Optec100-5 (Wipe Clean Headband with Impact Resistant Screen), and  
Optec100-6 (Washable Headband with Impact Resistant Screen)
- Notified body:** SATRA Technology Europe Ltd (2777)
- EU type examination cert:** CERTIFICATE PENDING
- Product description:** Consisting of a bioplastic headband, 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:**  
PENDING CERTIFICATION TO 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). ISO 16321-1:2021 clauses 4.4 (Cleaning and/or Disinfection), 7.1.3 (Area to be Covered by Face Protectors), 7.2 (Headbands and Harnesses), and 7.13 (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

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