

## DECLARATION OF CONFORMITY EC

No. 20554/2025

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### 1. Product Name and Model:

**Shower Protection Cover – Model No. SHWR-COVER-001**

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### 2. Importer:

**VATSPPEEDSL**

**Calle Antonio Salvador N99.1, 28026 Madrid, Spain**

**Email: [services@vatspeed-eu.com](mailto:services@vatspeed-eu.com)**

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### 3. This declaration of conformity is issued under the sole responsibility of the importer:

**VATSPPEEDSL**

**Calle Antonio Salvador N99.1, 28026 Madrid, Spain**

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### 4. Product Name and Photo:

**Shower Protection Cover**

**(Waterproof protective cover designed to keep wounds, casts, bandages, or medical dressings dry during showering. Made from flexible, skin-safe plastic materials with elastic or vacuum-seal closure.)**



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**5. Product complies with the following EU directives and regulations:**

- **General Product Safety Regulation (GPSR) EU 2019/1020**
  - **REACH Regulation (EC) No 1907/2006**
  - **RoHS Directive 2011/65/EU (if applicable to valve or pump components)**
  - **Packaging and Packaging Waste Directive 94/62/EC**
  - **Medical Device Regulation (EU) 2017/745 (only if marketed as a medical accessory)**
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**6. Product complies with the following standards:**

- **EN ISO 10993-1:2018 – Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (for skin contact materials)**
  - **EN 14683:2019+AC:2019 – General requirements for protective hygiene materials (if applicable)**
  - **EN IEC 63000:2018 – Technical documentation for RoHS compliance**
  - **ISO 9001:2015 – Quality management systems**
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**7. Additional Notes:**

**This shower protection cover is designed for safe, repeated household use and is made from non-toxic, waterproof, and hypoallergenic materials. The product meets essential EU safety and chemical compliance standards and is suitable for adults and children. Proper usage instructions and warnings are included in the packaging.**

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**Date: 2025-03-01**

**Place: Madrid, Spain**

**Authorized Signatory:**

**Name: Carlos Fernández**

**Position: Compliance Officer**

**Signature:**

*Carlos Fernández*

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