

DECLARATION OF CONFORMITY EC

No. 20554/2025

1. Product Name and Model:

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

2. Importer:

VATSPPEEDSL

Calle Antonio Salvador N99.1, 28026 Madrid, Spain

Email: services@vatspeed-eu.com

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

VATSPPEEDSL

Calle Antonio Salvador N99.1, 28026 Madrid, Spain

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.)



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.

Date: 2025-03-01

Place: Madrid, Spain

Authorized Signatory:

Name: Carlos Fernández

Position: Compliance Officer

Signature:

Carlos Fernández

CE