

DECLARATION OF CONFORMITY EC

No. 20475/2024

1. Product Name and Model:

Condom No. C-001

2. Importer:

VAT SPEED SL

Calle Antonio Salvador N99.1,28026Madrid,Spain

services@vatspeed-eu.com

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

VAT SPEED SL

Calle Antonio Salvador N99.1,28026Madrid,Spain

4. Product Name and Photo:



Condom

5. Product complies with the directives:

- General Product Safety Regulation (GPSR) EU 2019/1020
- Medical Device Regulation (MDR) EU 2017/745
- REACH Regulation EC No 1907/2006

6. Product complies with the standards:

- EN ISO 4074:2015 - Natural latex rubber condoms, requirements, and testing
- ISO 10993-1:2020 - Biological evaluation of medical devices
- ISO 13485:2016 - Quality management systems for medical devices
- EN ISO 10993-5:2009 - Tests for in vitro cytotoxicity
- EN ISO 10993-10:2013 - Tests for irritation and skin sensitization

7. Additional Notes:

This product has been tested and found to comply with the relevant EU directives and standards listed above. The Condom is made of high-quality materials to ensure safety, durability, and effective use, meeting the rigorous standards for medical devices within the EU.

Date:2024-01-12

Place: Madrid, Spain

Authorized Signatory:

Name: Carlos Fernández

Position: Compliance Officer

Signature:

Carlos Fernández

CE