EU Declaration of Conformity

1. **Product model: CarimasCE v1.3**

2. **Name and address of the manufacturer:**

The wellbeing services county of Southwest Finland, Business ID: 3221065-1, SRN: FI-MF-000038025
Kiinamyllynkatu 4-8
20520 TURKU
+358 (0)2 3131828
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3. **This declaration of conformity is issued under the sole responsibility of the manufacturer.**

4. **Object of the declaration:**
   Product: CarimasCE v1.3, unique UDI-DI identifier: 6438270-0001-PJ

5. **Risk category: IIb, rule 11**

6. **Intended Use:**

Used to illustrate left ventricular blood flow from dynamic PET images using O15-H2O tracer in adult patients.

7. **The device complies with Regulation (EU) 2017/745 on medical devices and that the conformity assessment procedure is in accordance with Annex IX.**

8. **Harmonized standards:**
   EN ISO 13485:2016 + A11:2021 (Quality management system)
   EN ISO 14971:2019 + A11:2021 (risk analyses)
   EN ISO 15223-1:2021 (marking symbols)

9. **Notified Body: Eurofins Electric & Electronics Finland Oy, nro 0537**

Certificate number: CR-03-1220-858-24

In Turku 27.11.2024