UKCA DECLARATION OF CONFORMITY

We,

MEDICOM SAS
Boulevard de la Chanterie – 49 124 Saint Barthélemy d'Anjou – France

Declare that the declaration of conformity is issued under our sole responsibility and relates to the following product:

SafeTouch Connect Vitals
Category III Personal Protective Equipment – Protective gloves
Class I Medical Devices – Medical gloves

Reference	Brand	Powder	Color	Packaging
1121	MEDICOM	Powdered	Natural	10 boxes of 100 units

MD Intended purpose: Single-use, non-sterile, powdered, latex examination gloves with textured fingertips, intended to cover the hands and the wrists of the healthcare professional during medical cares or examinations, in order to prevent the risk of cross-contamination.

PPE intended purpose: Single-use, non-sterile, powdered, latex protective gloves with textured fingertips, intended to protect the bearer against tested chemicals (type C) and microorganisms (bacteria, moulds and viruses).

The objects of the declaration described above comply with the following Union harmonisation legislations:

- Regulation 2016/425 on personal protective equipment, as amended to apply in GB
- UK Medical Device Regulation 2002

The following harmonised standards and technical specifications have been applied:

Medical Device	Personal Protective Equipment
EN 455-1	EN ISO 21420
EN 455-2	EN ISO 374-1
EN 455-3	EN ISO 374-2
EN 455-4	EN ISO 374-4
	EN 16523-1
	EN ISO 374-5
	ISO 16604

Conformity assessment procedure:

- **Personal protective equipment:**

  The notified body SATRA (2777) performed the EU type-examination (Module B) and issued the EU-type examination certificate n°2777/10468-05/E18-01.
  The product is subject to the conformity to type assessment procedure based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the notified body SATRA (2777).
  As stated by the UK government on November 14th 2022, products being CE marked by a notified body before December 31st 2024, do not require UKCA type examination certification by an Approved Body (UK). CE conformity assessment can be used as a basis for UKCA marking and the product can be placed on the UK market until the validity of the CE certificate expires or for three years (up to December 31st 2027).

- **Medical device:**

  The product is subject to the procedure set out in UK Medical Device Regulation 2002 and does not require a UKCA type examination certificate by an approved body.

Signed for and on behalf of: Sandrine Engels, President of Medicom Europe

Name: Yannick CHEVALIER

Function: European Quality, Regulatory and R&D Director

Signature:

Place of issue: Saint Barthélemy d'Anjou

Date of issue: 05/02/2024

Expiry date: 10/01/2027