UKCA DECLARATION OF CONFORMITY

We,

MEDICOM SAS
Boulevard de la Chanterie – 49124 Saint Barthélemy d'Anjou – France

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

SafeTouch Advanced Long
Category III Personal Protective Equipment – Protective gloves
Class I Medical Devices – Medical gloves

Reference	Brand	Powder	Color	Packaging
1131P	MEDICOM	Powder-free	Blue	10 boxes of 100 units

MD Intended purpose: Single-use, non-sterile, powder-free, nitrile medical glove, 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, powder-free, nitrile protective glove, intended to protect the bearer against tested chemicals (type B) including chemodrugs, microorganisms (bacteria, moulds and viruses) and radioactive contamination.

The object of the declaration described above complies 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
	EN 421
	ASTM D6978-05

Conformity assessment procedure:

- **Personal protective equipment:**

  The notified body CTC (0075) performed the EU type-examination (Module B) and issued the EU-type examination certificate n°0075/1467/162/04/22/0703 EXT 01/04/2022.
  The product is subject to the conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) under surveillance of the notified body CTC (0075).
  As stated by the UK government site, products falling under PPE regulation they will accept CE marking indefinitely into the UK.

- **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. For medical device class I they have imposed deadline for UKCA marking as 2030.

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: 08/04/2024

End of Validity date: 06/04/2027