



EU Declaration of Conformity

EU declaration of conformity No. **PK1:R01/18/11/2021**

1. Medical devices subject of this declaration:

Garmentec Technical Wear Poc-KIT Stretcher 966

2. Issued by:

**Garmentec Group Ltd
International House
Nunnery Drive
Sheffield S2 1TA
United Kingdom**

3. This declaration of conformity is issued under the sole responsibility of the manufacturer;
Garmentec

4. The EU Representative for this product is
Elara Europe, Dublin, D15 KV21, Ireland

5. Object of the declaration:

Garmentec (brand) Poc-KIT Stretcher (model) 966 (product code)

6. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation:

REACH+SVHC List 2019

Global Medical Device Nomenclature (GMDN) code – term: 13818 – Portable stretcher

Medicines and Healthcare products Regulatory Agency (MHRA) new device reference: 2019060501171594

7. Conformity is declared in relation to the following standards used in the assessment of the PPE product described in 4, above:

8. **EN 13688:2013**

The manufacturer self certifies the product described above as a Class 1 medical device under Rule 1 of the EU Medical Devices Regulation 2017/745.

9. **GTIN-13 Number** (UDI): 5070000280707:



10. Global Model Number 50700002807Poc-KIT966DD

Signed for and on behalf of Garmentec
Done at Sheffield, United Kingdom, on 18/11/2021

Mark Helders
International Procurement and Quality Coordinator