UK Declaration of Conformity

for the Glove Kit

We hereby declare, under the manufacturer's sole responsibility, that the products described in this document are in conformity with the applicable provisions of the **Medical Devices Regulations 2002 (SI 2002 No. 618, as amended),** and are manufactured and released in accordance with the Quality Management System in force on the date of issue of this declaration. The UKCA marking may be affixed.

PRODUCT NAME:	Glove Kit
LEGAL MANUFACTURER:	**COVVI LTD,** Unit 4 (Direct House), Quayside Business Park, George Mann Road, Leeds, LS10 1DJ, UK
EU SINGLE REGISTRATION NUMBER (SRN)	GB-MF-000033926
BASIC UDI-DI	506072613GMN1GK2Q
GLOBAL MEDICAL DEVICE NOMENCLATURE CODE	64736
APPLICABLE LEGISLATIONS AND STANDARDS	As per Appendix I – Applicable Legislations and Standards
CONFIGURATIONS & VARIANTS:	As per Appendix II – Product Listing/Schedule
INTENDED PURPOSE:	The COVVI Glove Kit is an accessory intended to be worn with the COVVI Hand to protect it from external contaminants and maintain device integrity.
MEDICAL DEVICE CLASSIFICATION	Class I [Rule 1]
NOTIFIED BODY	N/A
UKCA CERTIFICATE	N/A
UK APPROVED BODY NAME:	Not Applicable for Class I
UK APPROVED BODY IDENTIFICATION NUMBER:	Not Applicable for Class I
MEDICAL DEVICE REGULATION ASSESSMENT ROUTE	In conformity with the applicable requirements of the Medical Devices Regulations 2002 (SI 2002 No. 618, as amended), commonly referred to as UK MDR 2002.

Name Simon Pollard **Position** Group CEO

Signed  **Date** 02-Jul-2025 **Place** Leeds, United Kingdom

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Our statements in this document regarding compliance do not extend to, or apply to any product subjected to unintended contamination, misuse, neglect, or accident

Appendix I – Applicable Legislations and Standards

This product complies with the essential requirements of the following regulations and standards.

1. **Regulations**
    - **UK MDR 2002 –** The Medical Devices Regulations 2002
    - **EU MDD 93/42/EEC –** Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. Medical Device Directive
    - **EU MDR 2017/745** – Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
    - **21 CFR –** Title 21 Code of Federal Regulations (Parts 800-1299 as applicable)
2. **Standards**
    - **ISO 13485:2016 +A11:2021** – Medical devices. Quality management systems. Requirements for regulatory purposes
    - **ISO 14971:2019 +A11:2021** – Medical devices. Application of risk management to medical devices
    - **ISO/TR 24971:2020** – Medical devices. Guidance on the application of ISO 14971
    - **EN ISO 15223-1:2021** – Medical devices. Symbols to be used with information to be supplied by the manufacturer. General requirements
    - **EN ISO 20417:2021** – Medical devices, Information to be supplied by the manufacturer
    - **IEC 62304:2006/AMD1:2015–** Medical device software. Software life cycle processes
    - **MEDDEV 2.7/1 rev.4 June 2016** – Clinical Evaluation. A guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC
    - **BS EN 62366-1:2015+A1:2020** – Medical devices. Application of usability engineering to medical devices
    - **IEC 60601-1:2005 + AMD1:2012 + AMD2:2020** – Medical electrical equipment — Part 1: General requirements for basic safety and essential performance.
    - **BS EN 60601-1-2:2015+A1:2021** – Medical electrical equipment - General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic disturbances. Requirements and tests
    - **IEC 60601-1-11:2015/Amd1:2020** – Medical electrical equipment. Part 1-11: General requirements for basic safety and essential performance
    - **EN ISO 10993-1:2018** – Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process
    - **ISO 639:2023** – Language code, Codes for the representation of names of languages
3. **Unharmonized standards**
    - **ISO/TC 168 –** Prosthetics and orthotics
    - **ISO 29783 series** – Prosthetics and orthotics
    - **ISO 22523** – External limb prostheses and external orthoses: Requirements and test methods
    - **ISO 8548 series** – Prosthetics and orthotics
    - **ISO 8549 series** – Prosthetics and orthotics
    - **ISO 13405 series** – Prosthetics and orthotics

Appendix II – Product Listing/Schedule

Product Codes	Product Description	UDI-DI
GLLCA	COVVI Glove - Left Hand Large Carbon	5060726131629
GLLTG	COVVI Glove - Left Hand Large Titanium Grey	5060726131643
GLLWH	COVVI Glove - Left Hand Large White	5060726131650
GLMCA	COVVI Glove - Left Hand Medium Carbon	5060726131667
GLMRG	COVVI Glove - Left Hand Medium Rose Gold	5060726131674
GLMTG	COVVI Glove - Left Hand Medium Titanium Grey	5060726131681
GLMWH	COVVI Glove - Left Hand Medium White	5060726131698
GLSCA	COVVI Glove - Left Hand Small Carbon	5060726131704
GLSRG	COVVI Glove - Left Hand Small Rose Gold	5060726131711
GLSTG	COVVI Glove - Left Hand Small Titanium Grey	5060726131728
GLSWH	COVVI Glove - Left Hand Small White	5060726131735
GRLCA	COVVI Glove - Right Hand Large Carbon	5060726131742
GRLTG	COVVI Glove - Right Hand Large Titanium Grey	5060726131766
GRLWH	COVVI Glove - Right Hand Large White	5060726131773
GRMCA	COVVI Glove - Right Hand Medium Carbon	5060726131780
GRMRG	COVVI Glove - Right Hand Medium Rose Gold	5060726131797
GRMTG	COVVI Glove - Right Hand Medium Titanium Grey	5060726131803
GRMWH	COVVI Glove - Right Hand Medium White	5060726131810
GRSCA	COVVI Glove - Right Hand Small Carbon	5060726131827
GRSRG	COVVI Glove - Right Hand Small Rose Gold	5060726131834
GRSTG	COVVI Glove - Right Hand Small Titanium Grey	5060726131841
GRSWH	COVVI Glove - Right Hand Small White	5060726131858