UK Declaration of Conformity

for the COVVI Hand

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 The Electromagnetic Compatibility Regulations 2016 (SI 2016 No. 1091),** 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:	COVVI Hand
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	506072613GMN001WU
GLOBAL MEDICAL DEVICE NOMENCLATURE CODE	41497
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 Hand is intended for individuals with unilateral or bilateral upper limb loss or congenital limb deficiency. It is designed exclusively for use in exoprosthetic fittings of the upper limbs, providing functional and assistive support to users.
MEDICAL DEVICE CLASSIFICATION	Class I [Rule 12]
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

4. Test Reports & Certification

This document supported by the following test reports.

- **EMC Test Report No: 13400TR1– Eurofins E&E UK**
- **Radio Testing Report No: C13440TR1– Eurofins E&E UK**
- **EMC Test Certificate No: 13469TC1 – Eurofins E&E UK**
- **Safety Testing Report No: C13411TR1 – Eurofins E&E UK**
- **60601-1 Safety Testing Certificate No: C13622TC1 - Eurofins E&E UK**
- **60601-1-2 Test Certificate No: 13403TC1 - Eurofins E&E UK**
- **Ingress Protection Test Report No: CML-IPTR-18072-A – Eurofins E&E UK**
- **Ingress Protection Certificate No: CML-IPTC-18072-A – Eurofins E&E UK**
- **Environmental Test Report No: 105266 - Alphatech Ltd**
- **Environmental Test Certificate No: 105266 - Alphatech Ltd**

Appendix II – Product Listing/Schedule

Product Code:	Description:	UDI-DI
CV1LSQBLWH	COVVI Left Small Hand - Black Glove White Cover	5060726130240
CV1LMQBLWH	COVVI Left Medium Hand - Black Glove White Cover	5060726130257
CV1LLQBLWH	COVVI Left Large Hand - Black Glove White Cover	5060726130264
CV1RSQBLWH	COVVI Right Small Hand - Black Glove White Cover	5060726130271
CV1RMQBLWH	COVVI Right Medium Hand - Black Glove White Cover	5060726130288
CV1RLQBLWH	COVVI Right Large Hand - Black Glove White Cover	5060726130295
CV1LSQBLCA	COVVI Left Small Hand - Black Glove Carbon Cover	5060726130301
CV1LMQBLCA	COVVI Left Medium Hand - Black Glove Carbon Cover	5060726130318
CV1LLQBLCA	COVVI Left Large Hand - Black Glove Carbon Cover	5060726130325
CV1RSQBLCA	COVVI Right Small Hand - Black Glove Carbon Cover	5060726130332
CV1RMQBLCA	COVVI Right Medium Hand - Black Glove Carbon Cover	5060726130349
CV1RLQBLCA	COVVI Right Large Hand - Black Glove Carbon Cover	5060726130356
CV1LSQBLRG	COVVI Left Small Hand - Black Glove Rose Gold Cover	5060726130363
CV1LMQBLRG	COVVI Left Medium Hand - Black Glove Rose Gold Cover	5060726130370
CV1RSQBLRG	COVVI Right Small Hand - Black Glove Rose Gold Cover	5060726130394
CV1RMQBLRG	COVVI Right Medium Hand - Black Glove Rose Gold Cover	5060726130400
CV1LSQBLTG	COVVI Left Small Hand - Black Glove Titanium Grey Cover	5060726130424
CV1LMQBLTG	COVVI Left Medium Hand - Black Glove Titanium Grey Cover	5060726130431
CV1LLQBLTG	COVVI Left Large Hand - Black Glove Titanium Grey Cover	5060726130448
CV1RSQBLTG	COVVI Right Small Hand - Black Glove Titanium Grey Cover	5060726130455
CV1RMQBLTG	COVVI Right Medium Hand - Black Glove Titanium Grey Cover	5060726130462
CV1RLQBLTG	COVVI Right Large Hand - Black Glove Titanium Grey Cover	5060726130479
LN1LSQ	COVVI Loan Left Small Hand	5060726132107
LN1RSQ	COVVI Loan Right Small Hand	5060726132114
LN1LMQ	COVVI Loan Left Medium Hand	5060726132121
LN1RMQ	COVVI Loan Right Medium Hand	5060726132138
LN1LLQ	COVVI Loan Left Large Hand	5060726132145
LN1RLQ	COVVI Loan Right Large Hand	5060726132152